February 17, 2022 - Alaska Board of Pharmacy Meeting - Day 1

Alaska Division of Corporations, Business and Professional Licensing
https://us02web.zoom.us/meeting/register/tZ0qfuGuqzIsEtfRdEquYVOP52DLpmkV7kqK
Feb 17, 2022 9:00 AM - Feb 17, 2022 4:30 PM AKST

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STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

February 17, 2022

Meeting

Board Packet

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Leif Holm, PharmD (Vice Chair)	03/01/2015	03/01/2019	03/01/2023
Lana Bell, RPh (Secretary)	05/31/2016	03/01/2018	03/01/2022
James Henderson, RPh	03/01/2017	03/01/2017	03/01/2025
Justin Ruffridge, PharmD (Chair)	03/01/2020		03/01/2024
Tammy Lindemuth (Public Member)	01/24/2018	03/01/2018	03/01/2025
Sharon Long (Public Member)	03/01/2018		03/01/2022
Ashley Schaber	07/01/2021		03/01/2024

Updated 07/12/2021

State of Alaska 2022 STATE CALENDAR

State Holidays

Date	Holiday
01/01/2022	New Year's Day (observed 12/31/2021)
01/17/2022	MLK Jr.'s Birthday
02/21/2022	Presidents' Day
03/28/2022	Seward's Day
05/30/2022	Memorial Day
07/04/2022	Independence Day
09/05/2022	Labor Day
10/18/2022	Alaska Day
11/11/2022	Veterans' Day
11/24/2022	Thanksgiving Day
12/25/2022	Christmas Day (observed 12/26/2022)

Please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

Holiday
Payday

JANUARY

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ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

FEBRUARY 17, 2022 – DAY 1

Meeting ID: 897 9865 9683
Passcode: 274956

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

Board Members:

Justin Ruffridge
PharmD (Chair)

Leif Holm, *PharmD*
(Vice Chair)

Ashley Schaber,
PharmD

James Henderson, *RPh*

Lana Bell, *RPh*
(Secretary)

Tammy Lindemuth,
Public Member

Sharon Long, *Public Member*

Staff:

Laura Carrillo,
Executive Administrator

Heather Noe,
Occupational Licensing Examiner

Upcoming Meetings:

TBD

Meeting Details

Meeting Name: February 17, 2022 - Alaska Board of Pharmacy Meeting - Day 1

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 02/17/2022

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 02/17/2022 (Recess until 02/18)

Meeting Location: State Office Building, 333 Willoughby Ave, 9th Floor, Juneau, Alaska 99801 (tentatively planned in-person unless canceled due to COVID-19)

Meeting Registration Link:
https://us02web.zoom.us/meeting/register/tZ0qfuGuqzIsEtfRdEquYVOP52DLpmkV7kqK

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Ruffridge)
II. Agenda Item #2 – 9:02 a.m. Review/Approve Agenda (Chair Ruffridge)
III. Agenda Item #3 – 9:05 a.m. Ethics Disclosures (Chair Ruffridge)
IV. Agenda Item #4 – 9:10 a.m. Review/Approve Meeting Minutes (Chair Ruffridge)
V. Agenda Item #5 – 9:15 a.m. Industry Updates
    a. AKPhA (Renee Robinson/Brittany Keener)
    b. DHSS (Erin Narus/Coleman Cutchins)

c. NABP
    i. Interactive Forum (Ashley Schaber, participant)
    ii. Well-Being Index Report

VI. Agenda Item #6 – 10:00 a.m. Investigative Update (TBD)
    a. Investigative report
    b. License actions/agreements

VII. Agenda Item #7 – 10:30 a.m. Public Comment #1

VIII. Agenda Item #8 – 11:00 a.m. Division/Budget Update (Melissa Dumas)

IX. Agenda Item #9 – 11:30 a.m. Subcommittee Updates (Chair Ruffridge)
    a. Healthcare board chairs
    b. PDMP board chairs
    c. Controlled substances advisory subcommittee (Tammy Lindemuth)
    d. Compounding subcommittee

X. Agenda Item #10 – 12:00 p.m. Lunch

XI. Agenda Item #11 - 1:00 p.m. PDMP Update
    a. Board report
    b. System updates
    c. Awareness & feedback questionnaire
    d. Legislative report

XII. Agenda Item #12 – 1:30 p.m. Board Business (Chair Ruffridge)
    a. Application review
    b. Review lost/stolen Rx
    c. Correspondence
        i. Staffing/safety concerns (Anonymous)
        ii. eKit/first dose (Keith Koscielski)
        iii. MPJE efficiency (Rich Holt)
        iv. Telepharmacy/remote (Maimuna Bruce)
        v. Clozapine (FDA)
        vi. NABP
    d. Disciplinary matrix
    e. PDMP policies/procedures

f. PDMP disciplinary matrix

g. Media concerns/letter

h. Other

XIII. Agenda Item #13 – 4:15 p.m. Public Comment #2

XIV. Agenda Item #14 – 4:30 p.m. Recess until February 18 at 9:00 a.m.

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

CONFIDENTIAL

ETHICS SUPERVISOR DETERMINATION FORM

(Board or Commission Member)

Board or Commission: _____

Member Disclosing Potential Ethics Violation: _____

I have determined that the situation described on the attached ethics disclosure form

- ☐ does or would violate AS 39.52.110 - .190. Identify applicable statute below.
- ☐ does not or would not violate AS 39.52.110 - .190.

_____

Signature of Designated Ethics Supervisor (Chair)

_____

Printed Name of Designated Ethics Supervisor

Date: _____

COMMENTS (Please attach a separate sheet for additional space):

Note: Disclosure Form must be attached. Under AS 39.52.220, if the chair or a majority of the board or commission, not including the disclosing member, determines that a violation of AS 39.52.110-39.52.190 will exist if the member participates, the member shall refrain from voting, deliberating, or participating in the matter. A member will not be liable under the Ethics Act for action in accordance with such a determination so long as the member has fully disclosed all facts reasonably necessary to the determination and the attorney general has not advised the member, chair, or board or commission that the action is a violation. Forward disclosures with determinations to the State Ethics Attorney as part of your quarterly report. Quarterly reports are submitted to Litigation Assistant, Opinions, Appeals & Ethics, Department of Law, 1031 W. 4th Avenue, Suite 200, Anchorage, AK 99501.

Revised 2012

WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

EXECUTIVE BRANCH AGENCIES

Administration: Dave Donley, Deputy Commissioner

Commerce, Community & Economic Development: Amy Demboski, Assistant Commissioner

Corrections: April Wilkerson, Administrative Services Director

Education & Early Development: Bobi Jo Grimes, HR Consultant III

Environmental Conservation: Theresa Zimmerman, Human Resources Manager

Fish & Game: Samantha Gatton, Acting Admin Services Director

Health & Social Services: Kimberley King, Human Resource Manager

Labor & Workforce Development: Cathy Muñoz, Deputy Commissioner

Law: Maria Bahr, Assistant Attorney General

Military & Veterans Affairs: Stanley A. Wright, Special Assistant to the Commissioner

Natural Resources: Peter Caltagirone, Special Assistant

Public Safety: Kelly Howell, Special Assistant to the Commissioner

Revenue: Brad Ewing, Administrative Services Director

Transportation & Public Facilities:

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
    - Administrative Services Division
    - Division of Program Development
    - Information Systems and Services Division
    - Statewide Design and Engineering Services Division

Updated June 2020

ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.


Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.


Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than $150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than $150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.

This restriction on gifts does not apply to lawful campaign contributions.

 The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.

 Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.

 Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.

 Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.

 Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

 John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.

 The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.

 Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.

 The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.

 Andy takes the job, but specifies that he will have to work on another project.

Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

Disclosure Procedures

DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff*. If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

Complaints, Hearings, and Enforcement

COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to $5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

Benefit - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

Board or Commission - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

Designated Ethics Supervisor - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

Financial Interest - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

Immediate Family - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

Official Action - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

Personal Interest - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

For further information and disclosure forms, visit our Executive Branch Ethics web site or please contact:

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

EXECUTIVE BRANCH ETHICS ACT

Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the **2019 Designated Ethics Supervisors Handbook** (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
    1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the Department of Law ethics web site. If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
    1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

6/19

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE EMERGENCY MEETING

November 18, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on August 12, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

These are draft minutes and have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:01 a.m.**

The **November 18, 2021** videoconference was called to order by Chair, Dr. Ruffridge at 9:01 a.m.

Board members present, constituting a quorum:

Justin Ruffridge, PharmD #PHAP1787
Ashley Schaber, PharmD, #PHAP1697
Lana Bell, RPh #PHAP893 (joined at 10:02 a.m.)
James Henderson, RPh #PHAP1683
Tammy Lindemuth (joined at 10:02 a.m.)
Sharon Long

Division staff present:

Laura Carrillo, Executive Administrator
Heather Noe, Occupational Licensing Examiner
Lisa Sherrell, PDMP Manager
Sara Chambers, Division Director
Michael Bowles, Investigator
Marilyn Zimmerman, Paralegal

Members from the public present/registered:

Gretchen Glaspy, Alaska Pharmacists Association

Sheila Sinclair, Trilogy
Daniel Nelson, Self
Jessica Adams, Cardinal Health
Olga Brophy, Carrs/Safeway
Maimuna Bruce, Cardinal Health
Lorri Walmsley, Walgreens
Caren Robinson, AkPhA
Jennifer Adams, ISU
Samantha Chessie, N/A
Ryan Burke, PTCB
Lana Bell, BoP
Kevin McCabe, State House District 8
Sandy Taylor, Self
Angela Stephl, House of Representatives/Rep. McCabe
Bobbie Le, Pillpack
Coral Seaman
Shelley Tustison, Walmart
Ursula Chizhik, FLAVORx

Agenda Item 2 **Review/Approve Agenda** **Time: 9:02 a.m.**

The board reviewed the meeting agenda. Ms. Carrillo informed the board the division report/budget update may be at 1:30 p.m. instead of 1:00 p.m. as initially scheduled. Dr. Ruffridge called for a motion.

On a motion duly made by Sharon Long to approve the meeting agenda, seconded by Ashley Schaber, and approved unanimously, it was:

RESOLVED to accept the November 18, 2021 meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell				x
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

Agenda Item 3 **Ethics Disclosures** **Time: 9:03 a.m.**

Dr. Schaber disclosed that she is a member of AKPhA and the Past-President (incl. Board Member; By-Laws & Nominations Committee Chair) (through 2/22); Co-treasurer (through 2/22); and a member of the Legislative & Convention Committees.

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Agenda Item 4 **Review/Approve Minutes** **Time: 9:04 a.m.**

The board reviewed the draft September 23-24, 2021 meeting minutes.

On a motion duly made by Sharon Long to approve the meeting agenda, seconded by James Henderson, and approved unanimously, it was:

RESOLVED to accept the September 23-24th, 2021 meeting minutes as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell				x
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 1

Ms. Carrillo will send the approved minutes to Chair Ruffridge for signature and to the publications unit for posting to the website.

Agenda Item 5 **Investigative Report** **Time: 9:07 a.m.**

Investigator Bowles joined the meeting to present the board's investigative report, which included matters from September 10, 2021 through November 16, 2021. During this time, 22 matters closed and 23 remain open.

Agenda Item 6 **Board Business** **Time: 9:12 a.m.**

Disciplinary Matrix

Ms. Carrillo presented the draft disciplinary matrix she and Dr. Schaber began working on since the board's September meeting. Ms. Long expressed appreciation for the comprehensive work. Ms. Carrillo noted there were overlaps in violation types, for example: unprofessional conduct regulations in 12 AAC 52.920 also include matters related to fraud, negligence, and unlicensed practice. Ms. Carrillo inquired how the board wished to organize and structure the matrix. The

board agreed each potential violation category could be its own subcategory with a specified action.

Dr. Schaber emphasized the need to align unprofessional conduct language with the medical board as pharmacists move to become recognized as providers. On fine amounts, Dr. Ruffridge suggested an amount per day the licensee is in potential violation of the statute or regulation.

The board discussed prohibited use of certain language and symbols, such as "Rx" and "apothecary." The board contemplated what powers they hold to restrict, for example, grocery stores from selling health food bars, like the Rx Bar, without a pharmacy license. While the board agreed legal guidance would provide clarity, it was ultimately agreed the matter could be pursued further in the event a complaint of this nature is received.

Continuing Education Disciplinary Matrix

Paralegal, Marilyn Zimmerman, joined the board to discuss the continuing education disciplinary matrix that has been in existence for several years. Ms. Zimmerman recommended there be consistency in the matrix and that fine amounts align with the severity of the discipline. Ms. Zimmerman also explained that as currently written, the level of effort to research non-compliance matters, communicate with the licensee, and draft reprimand and consent documentation, often exceeds the outcome discipline when it results in $2,500 suspended and a fine of $25.00. The board agreed and discussed potential amendments to this matrix.

Dr. Ruffridge believes that continuing education is an incredibly important aspect of being licensed to perform patient care at a high level; the requirement to obtain these hours is not unreasonable or a difficult task. Dr. Ruffridge further suggested setting a base fine amount, stating it may be a motivating factor for licensees to complete their hours because there will be the same fine regardless of whether they missed 2 hours or 9 hours. Mr. Henderson agreed, adding there should be an additional fine amount for each hour per unit missed. Dr. Schaber also agreed, emphasizing the importance of distinguishing fine amounts between pharmacists and pharmacy technicians. Dr. Ruffridge suggested a base fine of $500 for pharmacists, plus $100 - $200 per credit hour missed. Ms. Lindemuth and Ms. Long suggested lower, but proportionate, amounts for pharmacy technicians.

On a motion duly made by Ashley Schaber to implement a continuing education base fine for pharmacists at $500, $100 for each credit hour missed, two mandatory audits, a consent agreement and reprimand, and for a pharmacy technician, a $125 base fine, $25 for each credit hour missed, two mandatory audits, a consent agreement and reprimand, seconded by James Henderson, and approved unanimously, it was:

> **RESOLVED to amend the continuing education disciplinary matrix by implementing base fines, per credit hour fines, mandatory audits, consent agreements, and reprimands for pharmacists and pharmacy technicians who fail to meet continuing education requirements.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion, however, Dr. Ruffridge suggested sending a notice through the ListService regarding this change.

TASK 2

Ms. Carrillo and Dr. Schaber will continue to work on the board's draft disciplinary matrix and will provide an update during its February 17-18, 2022 meeting.

TASK 3

Ms. Carrillo will send a notice through the ListServ with the board's update to its continuing education disciplinary matrix.

Application Review

The board had several tabled applications to discuss, including for regular licenses and emergency permits, and one request to approve an alternative continuing education schedule.

On a motion duly made by Justin Ruffridge to table the pharmacist application for Zachary Brown, #147445, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to table the pharmacist application for Zachary Brown.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 4

Ms. Carrillo will update Mr. Brown to inform him of his tabled application.

On a motion duly made by Justin Ruffridge in accordance with AS 44.62.310(c)(2), and seconded by James Henderson, the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Michael Bowles and Laura Carrillo were authorized to remain in the room.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

Off record at 10:30 a.m.
On record at 10:50 a.m.

Upon return from executive session, Chair Ruffridge clarified that no motions were made during executive session.

On a motion duly made by Ashley Schaber to deny the emergency pharmacist permit application for Katherine Ro #186368 per 12 AAC 52.110 as it is not possible to determine the emergency, seconded by Tammy Lindemuth, and denied unanimously, it was:

RESOLVED to deny the emergency pharmacist permit for Katherine Ro per 12 AAC 52.110.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

Dr. Ruffridge added that while there may not be an emergency, it is encouraged the applicant apply for the regular pharmacist license.

On a motion duly made by Ashley Schaber to deny the emergency pharmacy technician permit application for Elaine Lam #186146 per 12 AAC 52.110 as it is not possible to determine the emergency, seconded by Tammy Lindemuth, and denied unanimously, it was:

RESOLVED to deny the emergency pharmacy technician permit for Elaine Lam per 12 AAC 52.110.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no discussion.

On a motion duly made by Ashley Schaber to deny the emergency pharmacy technician permit application for Elizabeth Bonilla #186142 per 12 AAC 52.110 as it is not possible to determine the emergency, seconded by Tammy Lindemuth, and denied unanimously, it was:

RESOLVED to deny the emergency pharmacy technician permit for Elizabeth Bonilla per 12 AAC 52.110.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell		x		
Tammy Lindemuth		x		
James Henderson		x		
Ashley Schaber		x		
Leif Holm				x
Sharon Long		x		

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to deny the emergency pharmacy technician permit application for Madiha Ghaznavi #186193 per 12 AAC 52.110 as it is not possible to determine the emergency, seconded by Tammy Lindemuth, and denied unanimously, it was:

RESOLVED to deny the emergency pharmacy technician permit for Madiha Ghaznavi per 12 AAC 52.110.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell		x		
Tammy Lindemuth		x		
James Henderson		x		
Ashley Schaber		x		
Leif Holm				x
Sharon Long		x		

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to deny the emergency pharmacy technician permit application for Marlene Rivas #186152 per 12 AAC 52.110 as it is not possible to determine the emergency, seconded by Tammy Lindemuth, and denied unanimously, it was:

RESOLVED to deny the emergency pharmacy technician permit for Marlene Rivas per 12 AAC 52.110.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell		x		
Tammy Lindemuth		x		
James Henderson		x		
Ashley Schaber		x		
Leif Holm				x
Sharon Long		x		

The motion passed with no further discussion.

On a motion duly made by Ashley Schaber to deny the emergency pharmacy technician permit application for Senti Seminjuntak #186314 per 12 AAC 52.110 as it is not possible to determine the emergency, seconded by Tammy Lindemuth, and denied unanimously, it was:

RESOLVED to deny the emergency pharmacy technician permit for Senti Seminjuntak per 12 AAC 52.110.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell		x		

Tammy Lindemuth	x	
James Henderson	x	
Ashley Schaber	x	
Leif Holm		x
Sharon Long	x	

The motion passed with no further discussion.

TASK 5

Ms. Carrillo will send a copy of the emergency permit denial motions to Investigator Bowles.

On a motion duly made by James Henderson to approve the request for approval of an alternative continuing education schedule under 12 AAC 52.330 for licensee #154661, seconded by Sharon Long, and approved unanimously, it was:

> **RESOLVED to approve the alternative schedule for continuing education for #154661.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge		x		
Lana Bell		x		
Tammy Lindemuth		x		
James Henderson		x		
Ashley Schaber		x		
Leif Holm				x
Sharon Long		x		

The motion passed with no further discussion.

TASK 6

Ms. Carrillo will process the application for #154661 per approval of request for an alternative continuing education schedule.

<u>Renewal Review/Approval Process for "Yes" Responses</u>

Ms. Carrillo addressed this document relating to supervisory review and investigative referral of potential non-compliance matters. Ms. Carrillo explained the board had previously approved an earlier iteration during its August meeting, but that the policy on which it was based had recently been updated such that the language now applies to facilities in addition to individuals. The previous referral procedure required as a result of licensees providing an affirmative response to any of the professional fitness questions applied clearly to individuals, but not to pharmacies and facilities, e.g.: outsourcing facilities and third-party logistics providers.

On a motion duly made by Tammy Lindemuth to approve the updated iteration to the *Renewal Review/Approval Process for Professional Fitness Responses*, seconded by James Henderson, and approved unanimously, it was:

> **RESOLVED to approve the *Renewal Review/Approval Process for Professional Fitness Responses* as amended.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 7

Ms. Carrillo will file the final version of the Renewal Review/Approval Process for Professional Fitness Responses for reference during the renewal cycle.

Review of Lost/Stolen Rx

The board reviewed DEA 106 forms for CARRS Pharmacy, Mat-Su Medical Center, and Safeway Pharmacy #1820.

Legislation Lead

With legislative session imminent, Ms. Carrillo asked the board to identify a legislative lead for pharmacy-related matters the board may have to testify on. Dr. Ruffridge was the board's previous lead and expressed interest in continuing. Dr. Schaber volunteered as a back-up contact.

On a motion duly made by Lana Bell to designate Justin Ruffridge as lead legislative contact for the board and Ashley Schaber as its secondary contact, it was:

> **RESOLVED to appoint Justin Ruffridge and Ashley Schaber as the board's legislative leads.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			

James Henderson	x	
Ashley Schaber	x	
Leif Holm		x
Sharon Long	x	

The motion passed with no further discussion.

TASK 8

Ms. Carrillo will forward to the department's legislative liaison contact information for Dr. Ruffridge and Dr. Schaber as leads for the upcoming session.

Agenda Item 7 **Public Comment #1** **Time: 11:15 a.m.**

Representative Kevin McCabe:

Rep. McCabe thanked the board for their hard work and reaction to the last discussion [during the September 23-24, 2021 meeting], adding they are important to the healthcare system and appreciate recognizing the physician-patient relationship.

Daniel Nelson:

Daniel Nelson expressed concern about patients being forced to use out-of-state pharmacies by PBMs or forced to pay for these prescriptions, which tend to be much more expensive. Mr. Nelson expressed further concern about patients receiving prescriptions that are supposed to be frozen but arrive thawed or don't show up on time; prescriptions for which there has been no patient counseling offered or given; resident pharmacists or pharmacies not having any relationship with the out-of-state pharmacist or pharmacy; and cumbersome prior authorization processes. Mr. Nelson echoed Rep. McCabe's sentiments around his appreciation for the board's letter, but stated the joint letter with the Board of Nursing and Board of Dental Examiners would have more added weight with the participation of the Medical Board. Of concern with the joint letter is the incorrect statement around FDA approval for monoclonal antibodies as it is only emergency authorized, which he recognizes may be a small but important distinction. Lastly, Mr. Nelson expressed disappointment in timeliness of responses from the board of pharmacy staff, stating a 5-day return time is not acceptable.

Coral Seaman:

Ms. Seaman inquired whether there was a policy around keeping cards on file or whether there were encryption or other security requirements.

Chair Ruffridge called for break.

Off record at 11:30 a.m.
On record at 11:42 a.m.

Agenda Item #8 **Correspondence** **Time: 11:42 a.m.**

Letter to the board re: ivermectin

The board first reviewed a confidential letter from an individual regarding concerns about pharmacists refusing to fill certain medications as prescribed by their doctor. Dr. Ruffridge stated that ivermectin has become a moderately political issue and contemplated a response to the letter, and for which Ms. Lindemuth strongly advised there to be one. Dr. Ruffridge addressed the construction of obstacles as a result of refusals to fill, adding it may be an opportunity to explain, as attempted in the board's recent joint letter, that pharmacists have an obligation to review prescriptions and not fill them if the strength or supply day is deemed unsafe. Dr. Ruffridge recalled from previous public comments there was a hope the board of pharmacy would mandate that all pharmacists dispense every prescription a doctor orders, which is not a reasonable move; however, if there were a response from the board, it should be one to educate the individual on the pharmacy's ability to deny prescriptions.

Ms. Lindemuth reiterated her opinion that this is an important issue and where there is a misunderstanding, it is appropriate individuals be given clarity. Ms. Long added that doctors and patients have a relationship that must be respected and that there has been concern from patients that when pharmacists deny prescriptions, they are effectively practicing medicine without a license. Ms. Long reiterated the importance for pharmacists to make the effort to call prescribers before refusing to fill prescriptions. Dr. Ruffridge agrees there is a degree of trust for patients and prescribers, but still in many cases and even at the highest level of the courts, pharmacists have a legal corresponding responsibility.

Ultimately, the board wished to respond to the individual's concern.

DEA Notice of Proposed Rule Making: Telepharmacy

The DEA proposes regulations for controlled substances prescribed electronically and dispensed by a telepharmacy system. The proposed rulemaking is to consider creating a special or modified telepharmacy registration. Comments to the proposed rule making are due January 18, 2022.

NABP - .Pharmacy Initiative for Online Pharmacies

The NABP's .Pharmacy verified program verifies safe online pharmacies. At present, 33 state boards and colleges of pharmacy are participating in this program. Alaska has not yet participated.

Arkansas Correspondence Re: Monoclonal Antibodies

The Arkansas Board of Pharmacy is collaborating with their Dept. of Health and State Pharmacists Association on monoclonal antibodies, which are considered passive immunization treatments that fall under the ability for pharmacists to order. Dr. Ruffridge inquired about the legal request on pharmacists' ability to independently order and administer therapeutics. Ms. Carrillo stated guidance was provided that the PREP Act preempts any state limitations on providing treatments. Dr. Ruffridge requested clarification specifically on monoclonal antibodies.

TASK 9
Ms. Carrillo will draft a response to the individual who wrote with concerns that pharmacists are refusing medications to help treat COVID-19. Ms. Carrillo will then send it to the board for their review/approval.

TASK 10
Ms. Carrillo will follow-up with DOL on whether pharmacists can independently order and administer monoclonal antibodies under the PREP Act.

Chair Ruffridge called for lunch at 12:02 p.m.

Off record at 12:02 p.m.
On record at 12:40 p.m.

Agenda Item #10 **Subcommittee Updates** **Time: 12:40 p.m.**

Controlled Substances Advisory Subcommittee
Ms. Lindemuth provided an update on the CSAC; the committee is continuing to discuss gabapentin, marijuana, mitragynine, and kratom. With regards to marijuana, there are some discrepancies in the definition of 'cannabis', specifically around the amounts of THC in it, which impacts law enforcement activity. The CSAC is contemplating whether to bring the attention to the Governor or to the Marijuana and Alcohol Control Board. Gabapentin is still being discussed as a schedule Va. Dr. Ruffridge inquired what the purpose of the scheduling is, to which Ms. Lindemuth clarified it is to benefit law enforcement. Scheduling the mitragynine as a IIIa would make its distribution of a felony so that law enforcement can prosecute.

Agenda Item #11 **Profession Updates** **12:50 p.m.**

Alaska Pharmacists Association
Gretchen Glaspy shared that the combined position for the executive director for the AKPhA and UAA contact is still in recruitment. The annual convention is scheduled for February 11 – 13, 2022, in-person at the Anchorage Hilton. Applications for the Bowl of Hygia Award will be accepted through 12/01/2021 and there are additional seats available to apply for.

Agenda Item #10 **Subcommittee Updates** **12:55 p.m.**

Hearing nothing further for profession updates, the board of pharmacy returned to subcommittee updates.

Healthcare Board Chairs
Dr. Ruffridge stated the chairs group is continuing to meet bi-weekly. One area of discussion are the division-wide vacancies, which speaks to earlier concern during public comment around staff response time. The group continues to discuss treatment and prevention of COVID-19.

PDMP Board Chairs

Dr. Ruffridge highlighted the PDMP board chairs' current goal to move towards a unified agreement for which to prioritize investigative efforts. The uniform agreement is intended to standardize amongst the 6 affected licensing boards certain prescribing and dispensing practices that may be unsafe, including medication strength, dangerous combinations, multiple provider episodes, etc. Dr. Ruffridge stated this is a combined effort and the group continues to meet biweekly.

Agenda Item #13 **Regulations** **Time: 1:00 p.m.**

Chair Ruffridge moved to discussing regulations. Ms. Carrillo explained that the intent to pursue document is to provide a guide on future regulatory discussions and is to serve as a prompt for the board to clarify whether it wishes to continue looking into certain regulatory areas, including: drug takeback programs, refill of controlled substances, medical examiner/coroner access, and the .pharmacy verified website program.

New Regulations: Automated distribution kiosks

The board inquired whether pharmacies are currently able to install distribution kiosks. Ms. Carrillo recalled DOL indicated it is within their purview to regulate. Dr. Rich Holt, who drafted the language, was on the line and clarified that the DOL stated pharmacies cannot do this currently unless it is written into regulation. Dr. Holt emphasized the distinction between distribution kiosks and dispensing kiosks; distribution kiosks are what the board could regulate without a statute change. Dr. Holt also proposed amendments to 12 AAC 52.420 to incorporate security measures around them. Dr. Schaber stated that as the draft is written, the kiosk would be required to be physically located at a pharmacy in Alaska, suggesting this may be an appropriate route to go if out-of-state pharmacies are trying to expand their services. Mr. Henderson agreed it was a matter worth pursuing. The board ultimately agreed to continue pursuing this matter.

New Regulations: Refill of controlled substances (12 AAC 52.270)

As written, 12 AAC 52.270(d)(2) includes imitating language around refills of controlled substances. Dr. Ruffridge stated this is not necessary because 75 CFR Sec. 1306.22 under the DEA already has language around refills of controlled substances. Ruffridge stated that it is redundant to the federal rule; (d)(2) is limiting the ability for patients to receive refills on federally scheduled controlled substances and suggested rewording to the language. Mr. Henderson suggested simplifying the amendment by repealing the subsection altogether.

On a motion duly made by James Henderson to remove section 12 AAC 52.470(d)(2) on refills, "the drug is not a federal or state scheduled controlled substance.", seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to strike 12 AAC 52.470(d)(2).

	APPROVE	DENY	ABSTAIN	ABSENT

Justin Ruffridge	x	
Lana Bell	x	
Tammy Lindemuth	x	
James Henderson	x	
Ashley Schaber	x	
Leif Holm		x
Sharon Long	x	

The motion passed with no further discussion.

TASK 11

Ms. Carrillo will add automated distribution kiosks to the board's next agenda for February 17-18, 2022.

TASK 12

Ms. Carrillo will forward the regulation amendments striking 12 AAC 52.470(d)(2) to the division's regulations specialist.

Agenda Item #12 **Budget Report/Division Update** **Time: 1:30 p.m.**

Director Chambers explained the timing of having 4th quarter reports available between late October – mid November when the coverage is from April to June. This is because it takes time for year-end reconciliation of systems, documents, receipts, invoices, and payables to close out during a re-appropriation period in October and be reported on before the new fiscal year begins July 1. Director Chambers pointed to the biennium trend, which shows increased revenue for the two-year life of a license since FY14. Ms. Chambers observed the difference between non-renewal year license fees received in FY21 ($1,121,447) compared to FY19 ($213,770), noting the $900,000 difference. Ms. Carrillo stated the renewal year was extended through the end of September, which may explain the influx in revenue. The board's total revenue for the biennium is $1,752,552.

Direction Chambers directed the board to investigative expenditures, which is usually where volatility lies. This is now broken down into non-investigative expenditures and investigative expenditures. Non-investigative expenditures include staff time, travel, services, commodities, and capital outlay. Investigative expenditures increased drastically between FY19 and FY21. Ms. Carrillo stated this may be due to new facility license types referred to the investigative unit for potential change violations at the time of the extended renewal.

Dr. Ruffridge recalled from the last meeting the division's fee analysis and recommended fee changes. Looking at the board's surplus of $368,000 and how it compares to similarly operating programs like medical and nursing, where their surplus exceeds $1.1 million, Dr. Ruffridge commented the board's smaller surplus may not be stable over time and that it should avoid roller coaster fee changes. Director Chambers agreed and the board began discussing potential fee changes.

Dr. Ruffridge reiterated the board's interest in reducing the technician application and license fees because the cost may deter individuals from obtaining or renewing their license. Dr. Ruffridge noted that the application fee in 12 AAC 52.310(a)(1) applies to all license categories, including technicians, but suggested it could be reduced to zero to encourage more applicants to enter that career path. Dr. Schaber agreed, acknowledging cost is a barrier for technicians. Director Chambers acknowledged the board's intent to only reduce to zero the fee in (a)(1) for technicians and clarified she will ultimately approve the amendment since it is in centralized regulations. Mr. Henderson then suggested reducing fees for pharmacists and drug rooms. Ms. Long agreed with fee reductions.

New Pharmacist License	200	117	23,400	($100)	100
Renew Pharmacist License	200	1,059	211,800	($100)	100
New Wholesale Drug Distributor License	500	1	500		500
Renew Wholesale Drug Distributor License	500	15	7,500		500
New Pharmacy License	200	19	3,800		200
Renew Pharmacy License	200	132	26,400		200
New Drug Room License	200	10	2,000	($50)	150
Renew Drug Room License	200	41	8,200	($50)	150
Out of state Pharmacy	600	281	168,600		600
Renew Out of state Pharmacy	600	640	384,000		600
New Pharmacy Technician License	50	488	24,400	($25)	25
Renew Pharmacy Technician License	50	1,309	65,450	($25)	25

On a motion duly made by James Henderson to reduce the $200 initial pharmacist licensee fee by $100 to be $100, the $200 pharmacist renewal fee by $100 to be $100, the $200 initial drug room license fee by $50 to be $150, the $200 renewal drug room license fee by $50 to be $150, the $100 initial pharmacy technician application fee to $0, the $50 initial pharmacy technician license fee by $25 to be $25, and the $50 pharmacy technician renewal fee by $25 to be $25, seconded by Sharon Long, and approved unanimously, it was:

RESOLVED to accept the fee reductions for pharmacists, drug rooms, and pharmacy technicians.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm				x
Ashley Schaber	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 13

Ms. Carrillo will forward the board's motion and minutes excerpt on fee reductions to the regulations specialist.
Chair Ruffridge called for break at 2:40 p.m.

Off record at 2:40 p.m.
On record at 2:52 p.m.

Agenda Item #13 **Regulations** **Time: 1:00 p.m.**

New Regulations: Drug takeback programs (uncodified)
Ms. Carrillo stated DOL clarified the board could pursue drug takeback programs in regulation and develop a requirement for pharmacies to notify the board when they become a receptacle site. Dr. Ruffridge stated the process to obtain a receptacle registration under the DEA is already a cumbersome and onerous process. Since it is already highly regulated by the DEA, Dr. Ruffridge suggested there may not be a need to regulate this at the state level. Mr. Henderson agreed.

TASK 14
Ms. Carrillo will remove drug takeback programs as a future agenda item.

New Regulations: Medical examiner/coroner access to PDMP (uncodified)
Ms. Carrillo stated the proposed language as included in the board packet was suggested by DOL after a recent inquiry around whether medicolegal investigators can have access to the data on behalf of a medical examiner/coroner (ME/C). Guidance was previously provided in 2018 that delegates of ME/Cs could have access; however, it was more recently determined that medicolegal investigators specifically cannot have access because their scope is to determine jurisdiction, whereas ME/C access is permitted only to determine the manner and cause of death. Dr. Ruffridge agreed the proposed language was straight forward and that this could be pursued.

New Regulations: NAPBP's .Pharmacy and VIPPS programs
Ms. Carrillo clarified the .Pharmacy and VIPPS program would fall under statute changes since online pharmacies are located outside of the state; to *license* out-of-state pharmacies requires a statute change to update the registration category. Dr. Ruffridge expressed support for pursuing this change statutorily, stating it is the wave of the future. Mr. Henderson also agreed this is an area the board needs to regulate.

Ms. Carrillo suggested gathering information on the number of pharmacies currently offering online services so that the board has some data to pull from when seeking legislation in the future. Dr. Ruffridge also recommended having a representative from the NABP attend a board meeting to present on their .Pharmacy and VIPPS programs.

TASK 15
Ms. Carrillo will track the number of pharmacies providing internet services at the time of the next renewal.

TASK 16

Ms. Carrillo will reach out to the NABP to invite a representative to discuss the .Pharmacy and VIPPS program with the board during its February 17-18, 2022 meeting.

PDMP Regulations: (adopt 12 AAC 52.855 - .857 amendments)

The board reviewed the proposed changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857 as publicly noticed and included in the board packet.

On a motion duly made by James Henderson to adopt the changes to 12 AAC 52.855 – 12 AAC 52.857 as publicly noticed, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to adopt 12 AAC 52.855 – 12 AAC 52.857.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 17

Ms. Carrillo will sign the certification order and affidavit of board action for adopted changes to 12 AAC 52.855 – 12 AAC 52.857.

Part III PDMP Regulations: Third-party vendors

Ms. Carrillo summarized the proposed amended to 12 AAC 52.865 (reporting and reviewing PDMP information) which includes verbiage on PIC reporting to the PDMP on behalf of the employing pharmacy. The proposal introduces the term, "third-party vendor" as an authorized reporter for both pharmacies and prescribers. It also outlines the requirements for when zero reports must be submitted.

Part III PDMP Regulations: Veterinary reporting

Ms. Carrillo explained the additional section on reporting of veterinary prescription data using current ASAP format aligns with the board of veterinary examiner's recent discussions on reporting. Ms. Sherrell shared with the board that she was recently with a veterinary TTAC group and it seems most states already have the standards built into their reporting systems versus

looking at multiple screens for the information. Dr. Ruffridge explained pharmacy software systems are different; some are more stringent where you have one screen with owner information and a separate screen with the animal information; and others where you could simply add the first name of the animal, last name, and date of birth of the owner on one screen. Dr. Ruffridge stated it would be of interest to know how many systems differ. Ms. Carrillo commented that at the time mandatory registration was rolling out, there may not have been messaging to clearly articulate to pharmacies the reporting standards that must be included so that the fields required for review correlate to the data that's reported.

Part III PDMP Regulations: 42 CFR Part 2

Ms. Carrillo summarized the proposed changes to 12 AAC 52.865 relating to required reporting of substance use disorder (SUD) treatment to the PDMP, explaining DOL advised that the board is required to adopt regulations. Ms. Carrillo explained that while the data must be reported, prescribers must first obtain the patient's consent. Data reported to the PDMP effectively makes the database a lawful holder of data, which places additional requirements to comply with federal law.

Part III PDMP Regulations: Audit of PDMP compliance

Ms. Carrillo explained that this section introduces new audit authority for the board to periodically review, at the time of license renewal, compliance with registration and reporting requirements.

On a motion duly made by Ashley Schaber to approve the proposed amendments to 12 AAC 52.860, 12 AAC 52.865, and new audit regulations in 12 AAC 02, seconded by Tammy Lindemuth, and approved unanimously, it was:

> **RESOLVED to approve proposed amendments to reporting of PDMP information and compliance auditing.**

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 18

Ms. Carrillo will submit part III PDMP regulations to the regulation specialist for DOL review and public comment.

Military Regulations

Ms. Carrillo stated the military and emergency permit language was sent to the publications specialist for DOL review in late September, but there is no recent update to provide.

Other

Dr. Ruffridge stated the board of Board of Nursing regulation, 12 AAC 44.440, regarding removing the requirement to provide APRN credentials on a prescription order was ready for adoption as of 11/03/2021. Dr. Ruffridge also stated the Medical Board's update to 12 AAC 40.983 dealing with cooperative practice agreements took effect on 11/18/2021.

TASK 19

Ms. Carrillo will create a joint cooperative practice form for use by physicians and pharmacists and will create a checklist and process to endorse cooperative practice applications after approval by the State Medical Board.

TASK 20

Ms. Carrillo will share the draft documents with the Medical Board's EA, Natalie Norberg, to finalize the cooperative practice application, checklist, and policy/procedure. Ms. Carrillo will then provide an update to the board on this at its February 17-18, 2022 meeting.

Agenda Item #13 **Statutes** **Time: 2:48 p.m.**

White/brown bagging

The board discussed white/brown bagging and reviewed the draft written by the AKPhA's legislative group. Dr. Ruffridge expressed this being an area where the board should support the association's efforts on, as other states are doing. Dr. Schaber reiterated the issues these practices are creating with out-of-state pharmacies, particularly in the infusion setting where insurance companies are requiring expensive specialty medications to be filled and sent to non-resident pharmacies and then compounded by that pharmacy and dispensed to that patient—a white bagging practice. Some insurance companies are requiring medication to be shipped directly to the patient and then administered at the infusion pharmacy, which is brown-bagging. Dr. Schaber explained that medications being filled at specialty pharmacies outside of the state are not always in the best interest of the patient.

Dr. Schaber asked for a follow-up on the board's legal opinion request on white/brown bagging. Dr. Ruffridge recalled it had to do with whether regulating the practice fell within the board's purview or whether it was entirely a Division of Insurance matter. Ms. Carrillo stated the request was submitted after the September meeting but that she will request a follow-up.

TASK 21

Ms. Carrillo will follow up on the DOL request regarding white/brown bagging.

Technicians with national certification

Dr. Ruffridge stated it would be ideal for the AKPhA to add technician national certification to their expansion bill, HB 145, adding it should be recognized that as pharmacists take on more and more, as do technicians. Dr. Schaber agreed and stated recognizing this as a separate license category would align with what other states are doing. Mr. Henderson supports this.

On a motion duly made by Justin Ruffridge to support legislative pursuits of adding pharmacy technicians with national certification as a separate license category in order to regulate, support, and promote technicians obtaining additional education to become certified, seconded by Sharon Long, and approved unanimously, it was:

RESOLVED to support legislative efforts to create a separate license category for pharmacy technicians with national certification.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

Agenda Item #15 **Public Comment #2** **Time: 2:48 p.m.**

Sandy Taylor:

Ms. Taylor asked for clarification on how CMS affects mail order prescriptions, stating under her plan, she's not able to take her prescription to a local pharmacy. Dr. Ruffridge responded, stating it ties to the issue of white bagging, a patient choice issue that mandates patients receive their medications out-of-state, but that since CMS is not within the jurisdiction of states to regulate, it is hard to answer.

Coral Seaman:

Ms. Seaman stated it is important pharmacies are diligent about performing drug interaction screenings and understanding pharmacogenetics, how different genes affect's the body's response to certain medications. Ms. Seaman also expressed concern about positive ID requirements at the time of patient prescription pickup and about mail order drugs arriving in the mail inconsistent with temperature requirements.

Agenda Item #13 **Regulations** **Time: 4:15 p.m.**

New Regulations: Pharmacists-in-charge

Dr. Ruffridge returned to regulations to discuss pharmacist-in-charge requirements and limitations, including the length of time a PIC must be physically present, whether a pharmacy can be in charge of two or more pharmacies at the same time, mandatory breaks, tech-to-pharmacist ratios, and script count per day per pharmacists.

Dr. Schaber expressed support with pursuing regulations around workforce wellness and well-being, adding it has become a huge topic of discussion especially during the pandemic. Dr. Schaber shared that the American Pharmacist Association sent out a survey within the last year through state affiliates regarding workplace conditions and that it would be helpful to reach out to the AKPhA for those results to be shared with the board.

Ms. Carrillo asked why mealtimes weren't being provided as part of the pharmacy's policies already. Dr. Ruffridge stated they are not always provided, and state law does not require employers to provide mealtime breaks. Dr. Ruffridge added it can become a patient safety issue if pharmacists are working 10-12 hours with no food or mental break. Dr. Schaber inquired whether other prescribing boards have mandatory mealtimes in their regulations. Ms. Carrillo briefly reviewed regulations for medical and nursing, but didn't find mealtime language, adding it's not a licensing function. Dr. Ruffridge stated that if it is regulated, it creates an opportunity for pharmacists to file a complaint.

TASK 22

Ms. Carrillo will add PIC requirements and limitations to the next meeting agenda for February 17-28, 2022.

TASK 23

Ms. Carrillo will reach out to the AKPhA for results on the workforce conditions survey and will share it with the board during their February 17-18, 2022, meeting.

Agenda Item 13 **Administrative Business** **Time: 4:51 p.m.**

Task List Review

The board reviewed the task list from its September 23-24 meeting, which also included ongoing tasks from previous meetings. Dr. Ruffridge noted, during this November meeting, that several tasks on the list were completed.

Meetings

Dr. Ruffridge asked the board how they liked the one-day meeting. Dr. Schaber supported it and stated it was efficient. Dr. Ruffridge felt a little rushed but suggested that for meetings held in-person it would be ideal to meet for two days and for meetings held via Zoom to be one day.

ListServ Notices

Ms. Carrillo stated it might be helpful to start providing recaps of notices sent through the board's list serv. Ms. Carrillo shared the only item sent out was regarding the joint statement between the nursing and dental boards for treatment of COVID-19. The board agreed it would be helpful to continue having this as an agenda item.

TASK 24

Ms. Carrillo will submit a travel and meeting request for all board members to attend the February 17-18, 2022 in-person meeting in Juneau.

Agenda Item 17 **Adjourn** **Time: 4:55 p.m.**

Dr. Ruffridge adjourned the meeting at 4:55 p.m.

_____

Laura Carrillo, Executive Administrator Date

_____

Justin Ruffridge, Chair Date

APhA

WELL-BEING index

Pharmacist Well-being Index

State Report for State Boards of Pharmacy

NABP District Seven States

JANUARY 2022

For Every Pharmacist. For All of Pharmacy.

PWWR
PHARMACY WORKPLACE & WELL-BEING REPORTING

Pharmacy Workplace and Well-being Reporting

~ What is PWWR?

~ December 2021 Report I - Focusing on the Positive

What is PWWR?

Why was it developed?

* Pharmacists and pharmacy personnel workplace factors and well-being continue to be a critical, complex issue for the profession and patient safety.
* What is lacking in the research is to critically examine workplace factors to determine how they affect pharmacy personnel well-being and patient safety.
* Pharmacists and pharmacy personnel have expressed a desire to discuss and address workplace factors and concerns and offer possible solutions but do not do so because they are fearful of employer retribution. Your voice is critical to enhance and safeguard the pharmacy workplace.

How does it work?

* Submit a confidential and anonymous report on positive or negative experiences
* Collected and analyzed by the Alliance for Patient Medication Safety (APMS), a recognized and listed Patient Safety Organization (PSO),
* The PSO extends the strong confidentiality and privilege protections under the federal Patient Safety and Quality Improvement Act of 2005.
* Individual reports and data will not be released. Only aggregated, non-identifiable data from all reports will be made available to qualified researchers for the purposes of education, and the development of best practices and recommendations to enhance the pharmacy workplace.

Goal?

PWRR reports will be aggregated to form a pool of data that will be used to influence and educate our pharmacy community and leaders on meaningful and actionable changes. The positive and negative experiences and situations provided via PWWR reports will help to tell a collective, powerful story that hopefully will spark change and improvement in well-being and patient safety.

PWWR Report I

DECEMBER 2021

Reports Submitted

- October 6 through December 14, 2021
- 440 Completed
- Over 1,000 incomplete/abandon

Report Type

- Positive Experiences – 9
- Negative Experiences – 431

PWWR Report I

DECEMBER 2021

Focus on the Positive –What were the Types of Positive Report?

- **Communication, feedback, and psychology safety (3)**
  - Received positive feedback from supervisor about an action taken to keep patients safe or improve quality of medication use.
  - Had a positive patient interaction that improved the patient's understanding of the medication and its use. (2)

- **Preventing errors and improving quality (2)**
  - Targeted safety practices prevented a potential error involving a high alert medication.
  - Used clinical skills, training, and expertise to prevent a potential medication error from reaching the patient.

- **Safety and quality by design (4)**
  - Supervisor created a learning opportunity for me to grow professionally and/or as a person. (3)
  - Supervisor asked for my input before implementing a new workflow, policy, or other change in the pharmacy.

PWWR Report I

DECEMBER 2021

Focus on the Positive – What Were the Positive Effects of Positive Experiences?

The trend from these reports indicate that positive experiences have a positive effect on an individual's engagement, energy, leadership, and well-being. Reporters indicated that because of the positive experience they would be more likely to:

- Take actions that help co-workers have a similar positive experience.
- Be more vigilant for opportunities to improve quality and safety in our pharmacy.
- Invest more emotional energy in improving the patient experience.
- Increase engagement with and awareness of the pharmacy's safety goals.

Focus on the Positive – What Did We Learn?

- Eight of the nine reporters indicated that these positive experiences would have a *lasting positive effect* on their well-being.
- The other indicated that it would have a temporary positive effect on their well-being.

What is the Well-being Index for Pharmacy Personnel?

Research-validated online tool invented by Mayo Clinic

*100% anonymous
*Free/Do not have to be an APhA member
*Assess as often as the individual wants and track progress over time
*Access through website or through mobile app
*APhA launched at the WBI for Pharmacy Personnel in July 2019

How

*9-question assessment
*Takes just 5 minutes to complete
*APhA has added 3 optional questions on engagement with profession, workplace support of patient care services, and what APhA could do to help.

Measures dimensions of distress and well-being

*Likelihood of Burnout
*Severe Fatigue
*Suicidal Ideation
*Quality of Life
*Meaning in Work
*Work-Life Integration
*Risk of Medical Error
*Risk of Leaving Job
*Overall Well-Being

https://app.mywellbeingindex.org/...up
Invitation Code: APhA

What is the WBI for Pharmacy Personnel's Distress Percent?

Distress Percent represents the percentage of individuals with a WBI score greater than or equal to 5 – the score, determined through a validation question process, indicates a risk of high distress.

Distress Percent is the percentage of those who completed the WBI who are at *risk of high distress*. It can not be generalized to the entire pharmacy personnel population.

Why is this Important?

Pharmacists identified as being at a *risk of high distress* are at a:

- 3-fold higher risk of low quality of life
- 8-fold higher risk of burnout
- 2.5-fold higher risk of high fatigue
- 2.5-fold higher risk of intent to leave their current
- ***2-fold higher risk of medication error***

WELL-BEING index
https://app.mywellbeir /signup
Invitation Cod

Process Questions and Practice Distress Percent

January 2020
January 2021
January 2022

When asked to respond to the statement *My work environment is supportive of me fully performing patient care services,* how did those in District Seven respond?

WELL-BEING index

	STRONGLY AGREE			AGREE			DISAGREE			STRONGLY DISAGREE			NOT APPLICABLE		
	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022
National	*17.6%*	*20.6%*	*21.3%*	*37.5%*	*38.9%*	*39.6%*	*20.1%*	*18.5%*	*17.9%*	*16.8%*	*14.1%*	*13.4%*	*8.0%*	*8.0%*	*7.8%*
Alaska	0.0%	0.0%	0.0%	33.3%	38.9%	38.1%	6.7%	11.1%	9.5%	53.3%	44.4%	42.9%	6.7%	5.6%	9.5%
Idaho	25.7%	27.1%	28.1%	54.3%	50.0%	49.1%	5.7%	8.3%	8.8%	5.7%	8.3%	7.0%	8.6%	6.3%	7.0%
Montana	15.4%	25.0%	23.8%	23.1%	25.0%	23.8%	46.2%	35.0%	38.1%	7.7%	5.0%	4.8%	7.7%	10.0%	9.5%
Oregon	15.3%	20.8%	21.0%	27.1%	27.3%	28.4%	37.3%	35.1%	33.3%	16.9%	14.3%	14.8%	3.4%	2.6%	2.5%
Washington	13.2%	13.0%	16.0%	44.7%	47.8%	45.0%	19.7%	17.4%	18.0%	13.2%	13.0%	12.0%	9.2%	8.7%	9.0%
Wyoming	0.0%	18.2%	16.7%	33.3%	45.5%	50.0%	16.7%	9.1%	8.3%	0.0%	0.0%	0.0%	50.0%	27.3%	25.0%

When asked to respond to the statement *I am satisfied with my ability to regularly engage in my profession and establishing collegial relationships with pharmacists outside of my practice site,* how did those in District Seven respond?

WELL-BEING index

	VERY SATISFIED			SATISFIED			DISSATISFIED			VERY DISSATISFIED		
	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022
National	*14.3%*	*15.3%*	*15.7%*	*40.3%*	*42.9%*	*43.8%*	*34.8%*	*32.6%*	*31.4%*	*10.7%*	*9.2%*	*9.1%*
Alaska	0.0%	0.0%	0.0%	93.3	88.9%	85.7%	6.7%	11.1%	14.3%	0.0%	0.0%	0.0%
Idaho	22.9%	16.7%	17.5%	45.7%	41.7%	45.6%	22.9%	33.3%	29.8%	8.6%	8.3%	7.0%
Montana	7.7%	10.0%	9.5%	46.2%	45.0%	42.9%	46.2%	35.0%	38.1%	0.0%	10.0%	9.5%
Oregon	8.5%	13.0%	12.3%	39.0%	37.7%	39.5%	39.0%	39.0%	37.0%	13.6%	10.4%	11.1%
Washington	7.9%	7.6%	8.0%	42.1%	42.4%	43.0%	44.7%	43.5%	42.0%	5.3%	6.5%	7.0%
Wyoming	33.3%	27.3%	25.0%	50.0%	54.5%	50.0%	16.7%	18.2%	25.0%	0.0%	0.0%	0.0%

Distress Percent by Practice Setting
District Seven

WELL-BEING index

	Community-Chain			Community-Independent			Hospital/ Healthsystem			Academia		
	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022	Jan 2020	Jan 2021	Jan 2022
National	*51.61%*	*46.91%*	*46.61%*	*27.68%*	*26.71%*	*26.58%*	*29.02%*	*27.93%*	*27.95%*	*21.38%*	*21.27%*	*21.38%*
Alaska	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small
Idaho	46.15%	40.00%	40.00%	Sample too small	Sample too small	Sample too small	Sample too small	15.38%	26.47%	Sample too small	Sample too small	Sample too small
Montana	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small
Oregon	45.95%	51.47%	52.86%	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small
Washington	55.56%	58.93%	57.81%	41.67%	43.75%	36.84%	27.78%	35.48%	33.33%	21.05%	26.83%	34.04%
Wyoming	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small	Sample too small

DISTRESS PERCENT CHANGES

National and District

December 2021 versus January 2022

Changes in Distress Levels

As of January 2022

State	Change in Distress % December 2021 vs January 2022	Distress % January 2022	State Rank for Distress Level January 2022
Largest Increase in Distress Percent			
New Mexico	2.49%	31.58%	36
Vermont	1.62%	28.89%	43
Connecticut	0.81%	45.59%	4
Nevada	0.80%	56.36%	1
Georgia	0.46%	33.79%	24
Largest Decrease in Distress Percent			
Alabama	-0.86%	36.28%	17
Missouri	-0.53%	32.00%	33
Hawaii	-0.51%	42.17%	8
New York	-0.47%	30.74%	39
Tennessee	-0.38%	37.06%	16
NATIONAL	-0.05%	32.08%	----

Changes in Distress Levels – District Seven

As of January 2022

	Change in Distress % Dec 21 vs Jan 22	Distress % Jan 2022	Distress % State Rank Jan 2022	COVID-19 Vaccine Admin Jan 2022	Change in Distress % Nov 21 vs Dec 21	Distress % Dec 2021	Distress % State Rank Dec 2021	Distress % State Rank Nov 2021	Distress % State Rank Oct 2021	Distress % State Rank Sep 2021	Distress % State Rank Jul 2021	Distress % State Rank Jun 2021	Distress % State Rank Apr 2021	Distress % State Rank Feb 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Alaska	No Change	**25.00%**	**48**	**1343785**	1.32%	25.00%	48	49	49	49	49	49	49	50	49	49
Idaho	**0.32%**	**33.03%**	**31**	**2979370**	0.63%	32.71%	31	33	39	40	34	34	34	28	40	39
Montana	No Change	**40.63%**	**10**	**1771895**	No Change	40.63%	10	10	10	10	12	12	12	12	19 (t)	24
Oregon	**-0.18%**	**33.15%**	**29**	**8683555**	0.37%	33.33%	27 (t)	30	26	28	28	27	28	32	36	37
Washington	**-0.18%**	**40.09%**	**12**	**15477225**	-0.10%	40.27%	11	11	11	12	11	11	11	11	12	13
Wyoming	No Change	**18.18%**	**52**	**873365**	No Change	18.18%	52	52	51	51	52	50	51	52	~	~

Note: Historic data from 2020/2021 has been removed to allow space for current month.
Refer to previous months' reports or contact ashaughnessy@aphanet.org for data.

DISTRESS PERCENT MONTHLY REPORTS
State-Specific
January 2022 versus December 2021

PHARMACISTS WELL-BEING INDEX

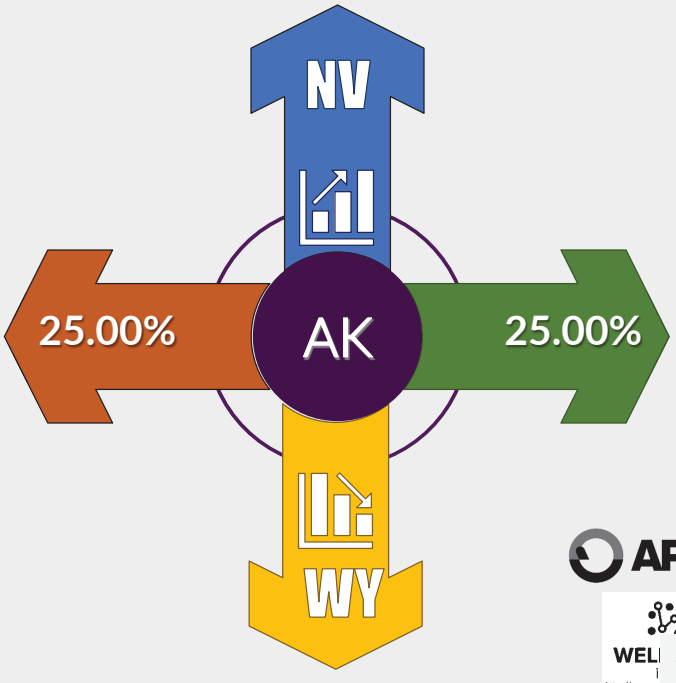
State Distress Percent*

January 2022

As of January 6, 2022, the Alaska distress percent was 25.00% (5th lowest) with 24 assessors. On this same date, the CDC reported 1,343,785 COVID-19 vaccines administered and 155,871 cases in the state.

December 2021

As of December 6, 2021, the Alaska distress percent was 25.00% (5th lowest) with 24 assessors. On this same date, the CDC reported 1,289,415 COVID-19 vaccines administered and 146,558 cases in the state.



State Comparison

As of January 6, 2022

Nevada is the highest at 56.36% (n=23)

Wyoming has the lowest 18.18% (n=15)

Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

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PHARMACISTS WELL-BEING INDEX

State Distress Percent*

January 2022

As of January 6, 2022, the Idaho distress percent was 33.03% (31st highest) with 65 assessors. On this same date, the CDC reported 2,979,370 COVID-19 vaccines administered and 323,965 cases in the state.

December 2021

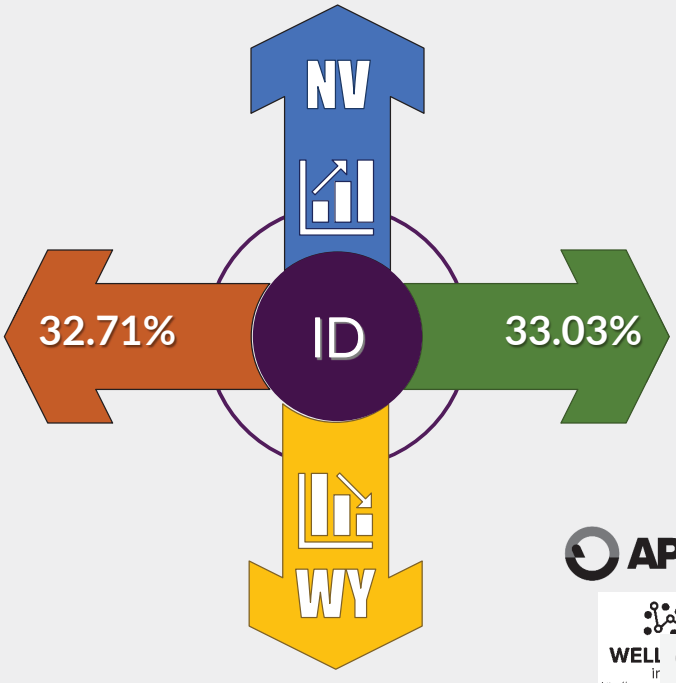
As of December 6, 2021, the Idaho distress percent was 32.71% (31st highest) with 65 assessors. On this same date, the CDC reported 2,782,680 COVID-19 vaccines administered and 308,869 cases in the state.

State Comparison

As of January 6, 2022

Nevada is the highest at 56.36% (n=23)

Wyoming has the lowest 18.18% (n=15)



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Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

State Distress Percent*

January 2022

As of January 6, 2022, the Montana distress percent was 40.63% (10th highest) with 26 assessors. On this same date, the CDC reported 1,771,895 COVID-19 vaccines administered and 1,054,485 cases in the state.

December 2021

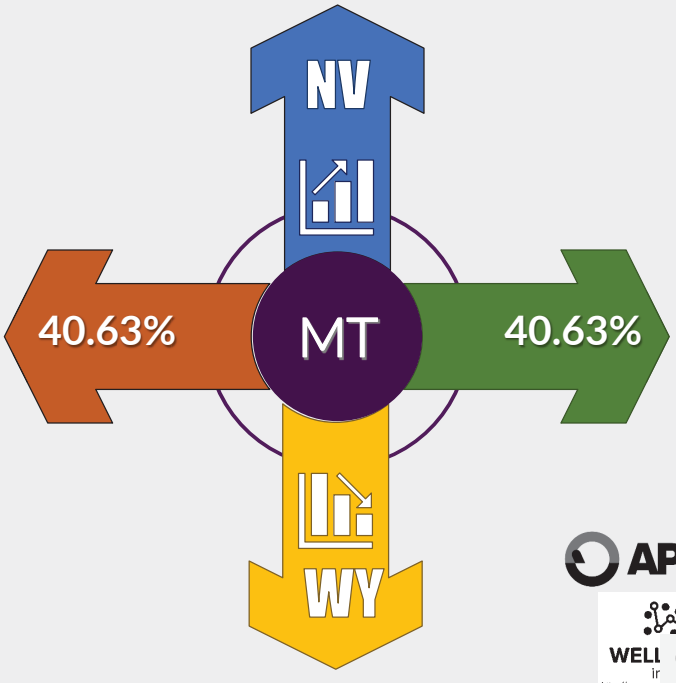
As of December 6, 2021, the Montana distress percent was 40.63% (10th highest) with 26 assessors. On this same date, the CDC reported 1,665,325 COVID-19 vaccines administered and 192,236 cases in the state.

State Comparison

As of January 6, 2022

Nevada is the highest at 56.36% (n=23)

Wyoming has the lowest 18.18% (n=15)



Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

State Distress Percent*

January 2022

As of January 6, 2022, the Oregon distress percent was 33.15% (29th highest) with 92 assessors. On this same date, the CDC reported 8,683,555 COVID-19 vaccines administered and 441,648 cases in the state.

December 2021

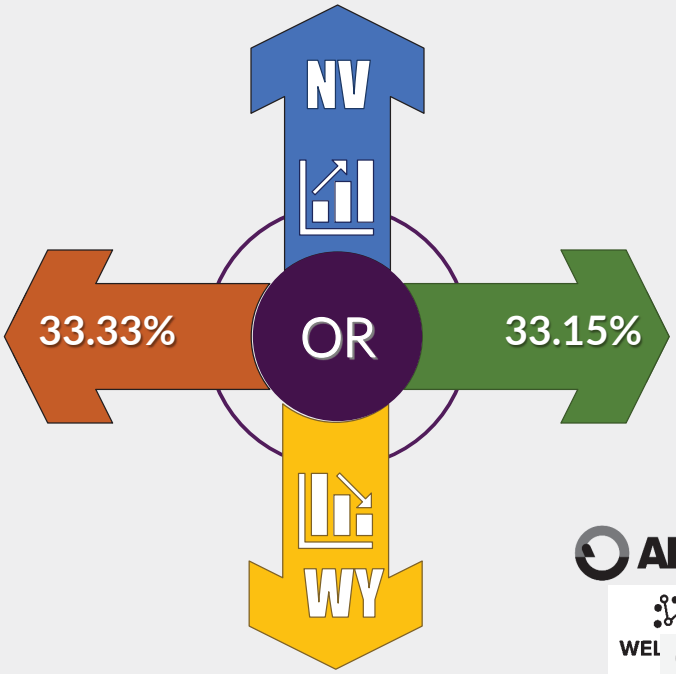
As of December 6, 2021, the Oregon distress percent was 33.33% (tied for 27th highest) with 91 assessors. On this same date, the CDC reported 8,072,925 COVID-19 vaccines administered and 394,569 cases in the state.

State Comparison

As of January 6, 2022

Nevada is the highest at 56.36% (n=23)

Wyoming has the lowest 18.18% (n=15)



Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

State Distress Percent*

January 2022

As of January 6, 2022, the Washington distress percent was 40.09% (12th highest) with 150 assessors. On this same date, the CDC reported 15,477,225 COVID-19 vaccines administered and 899,036 cases in the state.

December 2021

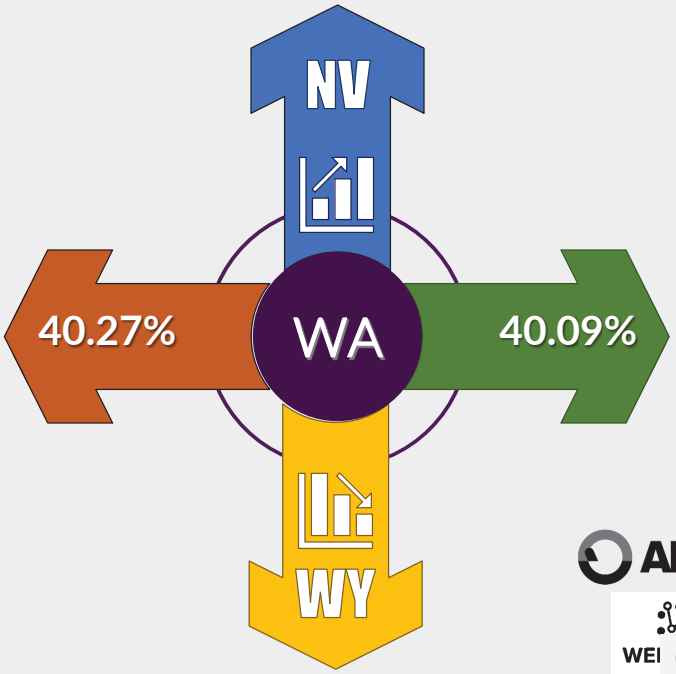
As of December 6, 2021, the Washington distress percent was 40.27% (11th highest) with 150 assessors. On this same date, the CDC reported 14,221,055 COVID-19 vaccines administered and 780,835 cases in the state.

State Comparison

As of January 6, 2022

Nevada is the highest at 56.36% (n=23)

Wyoming has the lowest 18.18% (n=15)



APhA

WEI 63 ING

https://app.m...s.org/signup
Invitation Code: APhA

Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

State Distress Percent*

January 2022

As of January 6, 2022, the Wyoming distress percent was 18.18% (the lowest) with 15 assessors. On this same date, the CDC reported 873,365 COVID-19 vaccines administered and 118,098 cases in the state.

December 2021

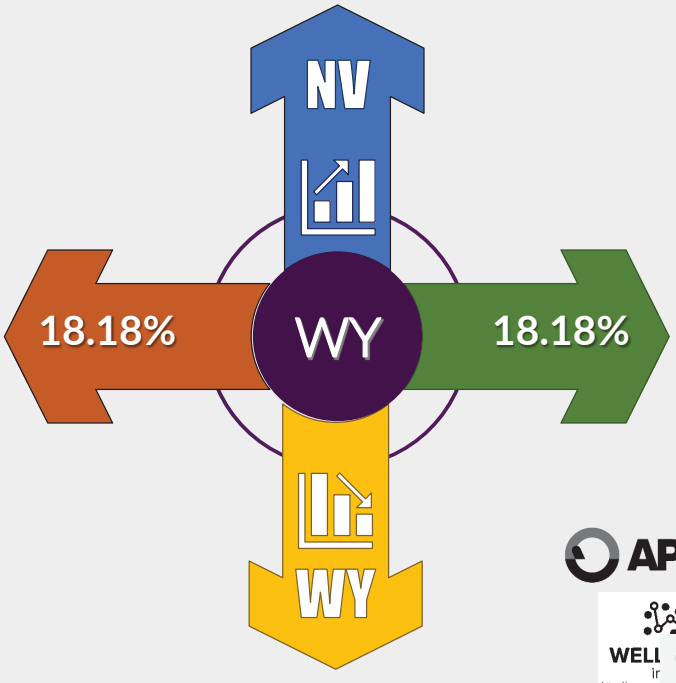
As of December 6, 2021, the Wyoming distress percent was 18.18% (the lowest) with 15 assessors. On this same date, the CDC reported 820,505 COVID-19 vaccines administered and 111,812 cases in the state.

State Comparison

As of January 6, 2022

Nevada is the highest at 56.36% (n=23)

Wyoming has the lowest 18.18% (n=15)



Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

Well-being Resources Promo Slides*

For Your Use in State Social Media and Periodicals

**Please do not change the content of these promotional slides*

PHARMACY WORKPLACE & WELL-BEING REPORTING

Your experiences – positive and negative – tell a powerful story!

Your experience can be the spark that helps change and enhance the pharmacy workplace, pharmacy personnel well-being, and patient safety.

Submit your experience report to
Pharmacy Workplace and Well-being Reporting.
www.pharmacist.com/pwwr

Your report is confidential, anonymous, and protected by the Alliance for Patient Medication Safety - a recognized national patient safety organization.

Share the PWWR link with your colleagues!

WELL-BEING index

Burnout is real.

Take advantage of APhA's online screening tool, invented by the Mayo Clinic, to evaluate your fatigue, depression, burnout, anxiety, and stress and assess your well-being.
It takes less than 5 minutes to answer 9 short questions.
It's 100% anonymous, free, and you do not need to be an APhA member.
Resources are available once you submit your assessment.

Well-being Index for Pharmacists, Student Pharmacists, & Pharmacy Technicians
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Or Scan

APhA

You're committed to pharmacy.
We're committed to your well-b
www.pharmacist.com/wellbe

THE STATE of ALASKA

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Fax: 907.269.8156

MEMORANDUM

DATE: February 07, 2022

TO: Board of Pharmacy

THRU: Greg Francois, Chief Investigator DS

FROM: Michael Bowles, Investigator DS MPB

RE: Investigative Report for the February 17, 2022 Meeting

The following information was compiled as an investigative report to the Board for the period of November 17, 2021 thru February 07, 2022; this report includes cases, complaints, and intake matters handled since the last report.

Matters opened by the Paralegals in Anchorage and Juneau, regarding continuing education audits and license action resulting from those matters are covered in this report.

OPEN - 34

Case Number	Violation Type	Case Status	Status Date
OUT OF STATE PHARMACY			
2022-000127	License application problem	Intake	02/04/2022
2022-000129	License application problem	Intake	02/04/2022
2021-000468	Violation of licensing regulation	Complaint	06/09/2021
2021-000944	Violation of licensing regulation	Complaint	10/08/2021
2021-001194	Violation of licensing regulation	Complaint	12/06/2021
2021-001204	Violation of licensing regulation	Complaint	12/07/2021
2021-001208	Violation of licensing regulation	Complaint	12/08/2021
2021-000054	License application problem	Investigation	04/28/2021
2021-000111	Violation of licensing regulation	Investigation	04/13/2021

PHARMACIST

2021-001241	Unprofessional conduct	Intake	12/13/2021
2021-001312	Fraud or misrepresentation	Complaint	02/03/2022

PHARMACY

2021-001187	Violation of licensing regulation	Intake	12/02/2021
2022-000030	Violation of licensing regulation	Intake	01/11/2022
2021-001125	Violation of licensing regulation	Complaint	11/16/2021
2021-001130	Unprofessional conduct	Complaint	12/06/2021
2021-000037	PDMP Violation	Monitor	01/21/2021
2021-000288	Falsified application	Monitor	01/11/2022
2021-000775	Compliance Inspection	Investigation	08/27/2021
2021-000776	Compliance Inspection	Investigation	08/27/2021
2021-000784	Compliance Inspection	Investigation	08/27/2021

PHARMACY TECHNICIAN

2021-001127	Falsified application	Complaint	11/16/2021
2021-001128	Falsified application	Complaint	11/17/2021
2019-000721	Falsified application	Investigation	02/09/2021
2019-000936	Falsified application	Investigation	02/11/2021

REGISTERED NURSE

2021-000380	Drug diversion	Intake	04/30/2021

WHOLESALE DRUG DEALER

2022-000128	License application problem	Intake	02/04/2022
2021-000733	Falsified application	Complaint	08/16/2021
2021-000938	Violation of licensing regulation	Complaint	10/07/2021
2021-001079	PDMP Violation	Complaint	11/02/2021
2021-001195	Violation of licensing regulation	Complaint	12/06/2021
2021-001210	Violation of licensing regulation	Complaint	12/08/2021
2021-000763	Violation of licensing regulation	Investigation	09/14/2021

2021-000940	Violation of licensing regulation	Investigation	01/03/2022
2021-000945	Violation of licensing regulation	Investigation	12/08/2021

Closed - 9

Case #	Violation Type	Case Status	Closed	Closure
OUT OF STATE PHARMACY				
2021-000943	Violation of licensing regulation	Closed-Complaint	12/21/2021	No Action - No Violation
PHARMACIST				
2021-000101	Falsified application	Closed-Investigation	02/04/2022	Application Withdrawn
2021-000532	Falsified application	Closed-Investigation	02/07/2022	Application Withdrawn
2021-001175	PDMP Violation	Closed-Investigation	01/10/2022	Advisement Letter
PHARMACIST INTERN				
2021-001020	License application problem	Closed-Intake	01/11/2022	Review Complete
PHARMACY				
2021-001201	Violation of licensing regulation	Closed-Intake	01/10/2022	Incomplete Complaint
PHARMACY TECHNICIAN				
2021-001230	License application problem	Closed-Intake	12/10/2021	Review Complete
WHOLESALE DRUG DEALER				
2021-000804	Violation of licensing regulation	Closed-Intake	02/03/2022	No Action - Lack of Jurisdiction
2022-000093	License application problem	Closed-Intake	01/28/2022	Other (See Abstract)

END OF REPORT

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Board of Pharmacy	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22 1st QTR
Revenue										
Revenue from License Fees	$ 802,230	$ 208,755	$ 1,010,985	$ 801,317	$ 213,770	$ 1,015,087	$ 631,105	$ 1,121,447	$ 1,752,552	$ 117,675
General Fund Received								$ -	-	$ -
Allowable Third Party Reimbursements	-	3,256	3,256	210	962	1,172	$ -	$ -	-	$ -
TOTAL REVENUE	$ 802,230	$ 212,011	$ 1,014,241	$ 801,527	$ 214,732	$ 1,016,259	$ 631,105	$ 1,121,447	$ 1,752,552	$ 117,675
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services	156,115	151,947	308,062	204,727	194,745	399,472	199,334	278,612	477,946	58,045
2000 - Travel	16,676	11,119	27,795	13,704	8,299	22,003	2,641	-	2,641	-
3000 - Services	13,361	14,293	27,654	21,960	27,781	49,741	45,283	46,180	91,463	48
4000 - Commodities	111	519	630	-	26	26	521	-	521	-
5000 - Capital Outlay	-		-	-		-	-	-	-	-
Total Non-Investigation Expenditures	186,263	177,878	364,141	240,391	230,851	471,242	247,779	324,792	572,571	58,093
Investigation Expenditures										
1000-Personal Services	68,935	63,727	132,662	68,679	69,997	138,676	57,738	106,494	164,232	26,386
2000 - Travel					-	-	1,260	-	1,260	-
3023 - Expert Witness	-	2,800	2,800	-	-	-	-	-	-	-
3088 - Inter-Agency Legal	1,451	23,355	24,806	-	3,062	3,062	2,537	1,269	3,806	-
3094 - Inter-Agency Hearing/Mediation	-	883	883	-	-	-	694	152	846	-
3000 - Services other					400	400	269	216	485	-
4000 - Commodities					-	-	-	-	-	-
Total Investigation Expenditures	70,386	90,765	161,151	68,679	73,459	142,138	62,498	108,131	170,629	26,386
Total Direct Expenditures	256,649	268,643	525,292	309,070	304,310	613,380	310,277	432,923	743,200	84,479
Indirect Expenditures										
Internal Administrative Costs	128,025	123,008	251,033	150,986	155,128	306,114	164,443	191,897	356,340	47,974
Departmental Costs	48,707	73,682	122,389	78,139	81,374	159,513	58,131	75,431	133,562	18,858
Statewide Costs	15,564	26,226	41,790	30,555	27,069	57,624	33,868	52,856	86,724	13,214
Total Indirect Expenditures	192,296	222,916	415,212	259,680	263,571	523,251	256,442	320,184	576,626	80,046
						-			-	
TOTAL EXPENDITURES	**$ 448,945**	**$ 491,559**	**$ 940,504**	**$ 568,750**	**$ 567,881**	**$ 1,136,631**	**$ 566,719**	**$ 753,107**	**$ 1,319,826**	**$ 164,525**
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ 201,479	$ 554,764		$ 275,216	$ 507,993		$ 154,844	$ 219,230		$ 587,570
Annual Increase/(Decrease)	353,285	(279,548)		232,777	(353,149)		64,386	368,340		(46,850)
Ending Cumulative Surplus (Deficit)	$ 554,764	$ 275,216		$ 507,993	154,844		$ 219,230	$ 587,570		$ 540,720
Statistical Information										
Number of Licenses for Indirect calculation	4,649	5,068		5,680	6,203		5,934	6,917		

Additional information:

*• Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **

• Most recent fee change: Fee change FY20

• Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program ch

Appropriation Name (Ex)	(All)
Sub Unit	(All)
PL Task Code	PHA1

Sum of Budgetary Expenditures	Object Type Name (Ex)		
Object Name (Ex)	**1000 - Personal Services**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	42,192.37		42,192.37
1014 - Overtime	246.07		246.07
1023 - Leave Taken	9,824.27		9,824.27
1028 - Alaska Supplemental Benefit	3,209.72		3,209.72
1029 - Public Employee's Retirement System Defined Benefits	710.39		710.39
1030 - Public Employee's Retirement System Defined Contribution	2,650.20		2,650.20
1034 - Public Employee's Retirement System Defined Cont Health Reim	1,729.88		1,729.88
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	533.76		533.76
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	10,121.42		10,121.42
1039 - Unemployment Insurance	171.82		171.82
1040 - Group Health Insurance	11,295.04		11,295.04
1041 - Basic Life and Travel	20.94		20.94
1042 - Worker's Compensation Insurance	486.81		486.81
1047 - Leave Cash In Employer Charge	889.43		889.43
1048 - Terminal Leave Employer Charge	727.76		727.76
1053 - Medicare Tax	730.55		730.55
1077 - ASEA Legal Trust	54.91		54.91
1079 - ASEA Injury Leave Usage	25.12		25.12
1080 - SU Legal Trst	6.99		6.99
1970 - Personal Services Transfer	(1,196.58)		(1,196.58)
3001 - Test Monitor/Proctor		-	-
3046 - Advertising		47.81	47.81
Grand Total	**84,430.87**	**47.81**	**84,478.68**

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Board of Pharmacy	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22 1st & 2nd QTR
Revenue										
Revenue from License Fees	$ 802,230	$ 208,755	$ 1,010,985	$ 801,317	$ 213,770	$ 1,015,087	$ 631,105	$ 1,121,447	$ 1,752,552	$ 233,265
General Fund Received								$ -	-	$ -
Allowable Third Party Reimbursements	-	3,256	3,256	210	962	1,172	$ -	$ -	-	$ -
TOTAL REVENUE	$ 802,230	$ 212,011	$ 1,014,241	$ 801,527	$ 214,732	$ 1,016,259	$ 631,105	$ 1,121,447	$ 1,752,552	$ 233,265
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services	156,115	151,947	308,062	204,727	194,745	399,472	199,334	278,612	477,946	115,235
2000 - Travel	16,676	11,119	27,795	13,704	8,299	22,003	2,641	-	2,641	-
3000 - Services	13,361	14,293	27,654	21,960	27,781	49,741	45,283	46,180	91,463	4,921
4000 - Commodities	111	519	630	-	26	26	521	-	521	-
5000 - Capital Outlay	-	-	-	-	-	-	-	-	-	-
Total Non-Investigation Expenditures	186,263	177,878	364,141	240,391	230,851	471,242	247,779	324,792	572,571	120,156
Investigation Expenditures										
1000-Personal Services	68,935	63,727	132,662	68,679	69,997	138,676	57,738	106,494	164,232	46,158
2000 - Travel					-	-	1,260	-	1,260	198
3023 - Expert Witness	-	2,800	2,800	-	-	-	-	-	-	-
3088 - Inter-Agency Legal	1,451	23,355	24,806	-	3,062	3,062	2,537	1,269	3,806	-
3094 - Inter-Agency Hearing/Mediation	-	883	883	-	-	-	694	152	846	1,193
3000 - Services other					400	400	269	216	485	-
4000 - Commodities					-	-	-	-	-	-
Total Investigation Expenditures	70,386	90,765	161,151	68,679	73,459	142,138	62,498	108,131	170,629	47,549
Total Direct Expenditures	256,649	268,643	525,292	309,070	304,310	613,380	310,277	432,923	743,200	167,705
Indirect Expenditures										
Internal Administrative Costs	128,025	123,008	251,033	150,986	155,128	306,114	164,443	191,897	356,340	95,949
Departmental Costs	48,707	73,682	122,389	78,139	81,374	159,513	58,131	75,431	133,562	37,716
Statewide Costs	15,564	26,226	41,790	30,555	27,069	57,624	33,868	52,856	86,724	26,428
Total Indirect Expenditures	192,296	222,916	415,212	259,680	263,571	523,251	256,442	320,184	576,626	160,093
						-			-	
TOTAL EXPENDITURES	**$ 448,945**	**$ 491,559**	**$ 940,504**	**$ 568,750**	**$ 567,881**	**$ 1,136,631**	**$ 566,719**	**$ 753,107**	**$ 1,319,826**	**$ 327,798**
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ 201,479	$ 554,764		$ 275,216	$ 507,993		$ 154,844	$ 219,230		$ 587,570
Annual Increase/(Decrease)	353,285	(279,548)		232,777	(353,149)		64,386	368,340		(94,533)
Ending Cumulative Surplus (Deficit)	$ 554,764	$ 275,216		$ 507,993	154,844		$ 219,230	$ 587,570		$ 493,037
Statistical Information										
Number of Licenses for Indirect calculation	4,649	5,068		5,680	6,203		5,934	6,917		

Additional information:

- *Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **
- *Most recent fee change: Fee change FY20*
- *Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and progr*

Appropriation Name (Ex)	(Multiple Items)
Sub Unit	(All)
PL Task Code	PHA1

Sum of Budgetary Expenditures	Object Type Name (Ex)			
Object Name (Ex)	**1000 - Personal Services**	**2000 - Travel**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	79,347.56			79,347.56
1014 - Overtime	419.22			419.22
1023 - Leave Taken	17,623.08			17,623.08
1028 - Alaska Supplemental Benefit	5,980.51			5,980.51
1029 - Public Employee's Retirement System Defined Benefits	1,787.59			1,787.59
1030 - Public Employee's Retirement System Defined Contribution	4,856.61			4,856.61
1034 - Public Employee's Retirement System Defined Cont Health Reim	2,967.68			2,967.68
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	978.26			978.26
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	18,743.56			18,743.56
1039 - Unemployment Insurance	316.35			316.35
1040 - Group Health Insurance	24,951.37			24,951.37
1041 - Basic Life and Travel	46.24			46.24
1042 - Worker's Compensation Insurance	889.22			889.22
1047 - Leave Cash In Employer Charge	1,658.14			1,658.14
1048 - Terminal Leave Employer Charge	1,357.40			1,357.40
1053 - Medicare Tax	1,354.54			1,354.54
1077 - ASEA Legal Trust	96.69			96.69
1079 - ASEA Injury Leave Usage	25.12			25.12
1080 - SU Legal Trst	11.18			11.18
1970 - Personal Services Transfer	(2,017.91)			(2,017.91)
3001 - Test Monitor/Proctor			-	-
3044 - Courier			3.55	3.55
3046 - Advertising			647.29	647.29
3094 - Inter-Agency Hearing/Mediation			1,193.50	1,193.50
2002 - In-State Employee Lodging		198.00		198.00
3100 - Inter-Agency Safety			4,270.00	4,270.00
Grand Total	**161,392.41**	**198.00**	**6,114.34**	**167,704.75**

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Prescription Drug Monitoring Program	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21	Biennium	FY 22 1st QTR
Revenue										
Revenue from License Fees			$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 191,320	$ 217,470	$ 15,535
General Fund Received								$ -	-	$ -
Allowable Third Party Reimbursements	-	-	-	-	-	-	$ -	$ -	-	$ -
TOTAL REVENUE	$ -	$ -	$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 191,320	$ 217,470	$ 15,535
Expenditures										
Non Investigation Expenditures										
1000 - Personal Services			-	-	6,043	6,043	41,343	(238)	41,105	1,280
2000 - Travel			-	-	-	-	796	-	796	-
3000 - Services			-	-	11	11	6,155	1,966	8,121	300
4000 - Commodities			-	-	-	-	-	-	-	-
5000 - Capital Outlay	-		-	-		-	-	-	-	-
Total Non-Investigation Expenditures	-	-	-	-	6,054	6,054	48,294	1,728	50,022	1,580
Investigation Expenditures										
1000-Personal Services			-		-	-	-	-	-	-
2000 - Travel					-	-	-	-	-	-
3023 - Expert Witness			-	-	-	-	-	-	-	-
3088 - Inter-Agency Legal			-	-	-	-	-	-	-	-
3094 - Inter-Agency Hearing/Mediation			-	-	-	-	-	-	-	-
3000 - Services other					-	-	-	-	-	-
4000 - Commodities					-	-	-	-	-	-
Total Investigation Expenditures	-	-	-	-	-	-	-	-	-	-
Total Direct Expenditures	-	-	-	-	6,054	6,054	48,294	1,728	50,022	1,580
Indirect Expenditures										
Internal Administrative Costs			-		-	-	-	-	-	-
Departmental Costs			-		-	-	-	-	-	-
Statewide Costs			-		-	-	-	-	-	-
Total Indirect Expenditures	-	-	-	-	-	-	-	-	-	-
						-			-	
TOTAL EXPENDITURES	$ -	$ -	$ -	$ -	$ 6,054	$ 6,054	$ 48,294	$ 1,728	$ 50,022	$ 1,580
Cumulative Surplus (Deficit)										
Beginning Cumulative Surplus (Deficit)	$ -	$ -		$ -	$ -		$ 84,711	$ 62,567		$ 252,159
Annual Increase/(Decrease)	-	-		-	84,711		(22,144)	189,592		13,955
Ending Cumulative Surplus (Deficit)	$ -	$ -		$ -	84,711		$ 62,567	$ 252,159		$ 266,114
Statistical Information										
Number of Licenses for Indirect calculation					-	-	-	-		

Additional information:

*• Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **

• Most recent fee change: No fee change since FY18

• Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program ch

CVSHealth

11/23/2021

Drug Enforcement Administration
1630 East Tudor Road
Anchorage, AK 99507
(907) 271-3097

RE: Pharmacy # 17404
1801 E PARKS HWY
WASILLA, AK 99654-7350
DEA # FA5754785
State License # 113890
Date of Loss on Initial Notification: 10/15/2021

Dear Sir/Madam,

On 10/15/2021, we faxed an initial notification of controlled substance theft or potentially significant loss from the CVS pharmacy referenced above.

The investigation of this matter remains open. I will continue to provide an update every forty five (45) days and once the investigation is complete will update you on our findings, either via a DEA-106 or letter of conclusion.

If you require additional information, please contact the Pharmacy Supervisor/District Leader at the following email:

Ryan Davis
Ryan.Davis@CVSHealth.com

Very truly yours,

Courtney Swindells

Courtney Swindells, CPhT Lead Coordinator, Drug Loss Program Team

Enclosure
CC: Drug Loss Program: Drug_Loss_Program@CVSCaremark.com or 401-216-3692
Arkansas State Board of Pharmacy

only valid if it identifies the number to which the request relates, and if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within 30 days of receipt.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** *(prior report dated)*: 2PZ905TKRFZ

1. **DEA Registration Number:** FP6653958

Name of Business: PMOA INC.

Address: 676 S. UNIVERSITY BLVD

City: MOBILE **State:** AL **ZIP Code:** 36609

Point of Contact: JASON HODGES

Email Address: JASON.HODGES@MITCHELL.COM **Phone No.:** 8004868792

Date of the Theft or Loss (*or first discovery of theft or loss*): November 30, 2021 **Number of Thefts and Losses in the past 24 months:** 0

Principal Business of Registrant: RETAIL PHARMACY

2. **Type of theft or loss:** LOSS IN TRANSIT:

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: FED-EX

Telephone Number of Common Carrier: 8004633339 Package Tracking Number: 286513533504

Have there been losses in transit from this same carrier in the past? ☐ No ☒ Yes *(If yes, how many, excluding this theft or loss?)*: 2

Was the package received and accepted by the consignee? ☒ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: PATIENT

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier:

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 23

6. **Were any pharmaceuticals or merchandise taken?** ☐ No ☒ Yes *(Est. Value)*: 23

7. **Was theft reported to Police?** ☐ No ☒ Yes *(If yes, fill out the following information)*:

Name of Police Department: MOBILE POLICE DEPARTMENT Police Report number: M2211200048

Name of Responding Officer: JONATHAN THOMAS Phone No.: 2512087211

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☒ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	OXYCODONE-ACETAMINOPHEN 10-325 MG TABL	31722095105	OXYCODONE HCL/ACETAMINOPHEN	10 MG-325 MG	TABLET	120

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

PRESCRIPTION VIAL WITH PHARMACY LOGO AND ALL REQUIRED INFORMATION. PHARMACY LOGO ON PACKAGE INSERT, PACKING SLIP, INTERIOR SHIPPING LABEL WITH BAR CODE.

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

THE MEDICATION IS PACKAGED IN STANDARD COURIER BOX OR NON-DESCRIPT BOX WITH SECURITY TAPE

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

THE PACKAGE WAS LOST IN TRANSIT (TRACKING NUMBER 286513533504). FED-EX SHOWS THE PACKAGE ARRIVING IN MEMPHIS HUB AT 1:08AM ON 11/24/2021. THE PACKAGE THEN SHOWS NO FURTHER MOVEMENT.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: JASON HODGES

Title: DIRECTOR OF PHARMACY OPERATIONS

Date Signed: December 01, 2021

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☒ **New Report** ☐ **Amendment Key** *(prior report dated)*: 3LHFLSDMMNRG

RECEIVED
Juneau
JAN 11 2022
CBPL

1. **DEA Registration Number:** FC1681813

Name of Business: COSTCO WHOLESALE CORPORATION

Address: 5225 COMMERCIAL BLVD

City: JUNEAU **State:** AK **ZIP Code:** 99801

Point of Contact: ROBERT J BAARS

Email Address: W107PHM@COSTCO.COM **Phone No.:** 9077802261

Date of the Theft or Loss *(or first discovery of theft or loss)*: December 20, 2021 **Number of Thefts and Losses in the past 24 months:** 1

Principal Business of Registrant: CHAIN PHARMACY

2. **Type of theft or loss:** EMPLOYEE THEFT (OR SUSPECTED):

3. **Loss in Transit.** *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).
If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. **If this was a robbery, were any people injured?** ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. **Purchase value to Registrant of controlled substances taken?:** $ 57

6. **Were any pharmaceuticals or merchandise taken?** ☐ No ☒ Yes *(Est. Value)*: 57

7. **Was theft reported to Police?** ☒ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

8. **Which corrective measure(s) have you taken to prevent a future theft or loss?**

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☒ Secured Controlled Substances within safe.
- ☐ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

NDC 31722-0954-01 METHYLPHENIDATE ER 36 MG 100 CT BOTTLE UNOPENED

RECEIVED
Juneau
JAN 11 2022
CBPL

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

IT IS UNCLEAR AT THIS TIME AND IS BEING RESEARCHED, I DONT SUSPECT THEFT OR DIVERSION. I BELIEVE THE UNOPENED BOTTLE FELL DOWN INTO THE RECENT INMAR RETURNS (155 TABS EXPIRED OF ANOTHER NDC SENT BACK IN NOVEMBER 2021) AND SOMEHOW WAS ADDED TO THE RECENT EXPIRED BAG (DOUBLE COUNTED THE FULL BOTTLE?). WE ARE REACHING OUT TO INMAR TO SEE IF THE ADDITIONAL BOTTLE WAS IN THE RETURN.

NDC 31722-0954-01 METHYLPHENIDATE ER 36 MG 100 CT BOTTLE UNOPENED

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 106 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: ROBERT J BAARS

Title: PHARMACY MANAGER

Date Signed: December 20, 2021

NOTICE: In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information

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Privacy Act Information

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Controlled Substances may result in penalties under Section 402 and 403 of the Controlled Substances Act

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

LIST OF CONTROLLED SUBSTANCES LOST

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
1	METHYLPHENIDATE ER 36 MG TAB	31722095401	METHYLPHENIDATE HCL	36 MG	TABLET, SR OSI	100

DEA FORM-106 *(Previous editions are obsolete.)*

From:	Licensed RPh in Your State
To:	help@nabp.pharmacy
Subject:	Staffing and Public Safety Concerns in Chain Retail Pharmacies with Proposed Solutions
Date:	Monday, December 20, 2021 7:42:45 AM
Attachments:	Staffing and Public Safety Concerns in Chain Retail_final_12.17.21.pdf

Dear NABP and Executive Directors of State Boards of Pharmacy,

Please see attached a document prepared by a licensed pharmacist in your state that outlines current issues with staffing and public safety concerns in chain retail pharmacies, as well as some proposed ideas as starting points for solutions.

It is high time that our Boards of Pharmacy across the country defended the pharmacist and pharmacy technician licensees who have been working in understaffed chain pharmacies for years, putting the public in harm's way of medication and vaccination errors.
The need for our Boards of Pharmacy to take action against chain retail pharmacies is now. Pharmacists and pharmacy technicians have been lauded as "healthcare heroes" during the Covid-19 pandemic and are administering 2/3rd of all Covid-19 vaccines to Americans all across the United States. The demand for vaccines and boosters is at an all-time high with the new emergence of the omicron variant. And yet working conditions in retail chain pharmacies have not changed and continue to place profits over people and put patients at risk, as evidenced by increasing reports and news articles about errors with regards to vaccine administration and medication dispensing.

Please, read this document and discuss the points in it at your next meeting, so we can work together to protect the public by creating better working conditions for the pharmacists and pharmacy technicians who serve them.

Respectfully yours,

A Licensed Pharmacist in Your State,
One of thousands of licensed pharmacists crying out for better working conditions so we can do our jobs and protect the public
And one of thousands of licensed pharmacists who are speaking anonymously because of the real threat of retaliation by our employers for trying to protect the public by warning them about the current situation in retail chain pharmacies

Staffing and Public Safety Concerns in Chain Retail Pharmacies

Prepared by a Licensed Pharmacist in Your State

The Problem: Chain Pharmacies Are Putting Profits Above Public Health and Patient Safety

- Several news articles on this topic, inc NY Times, over the last several years
  - ***How Chaos at Chain Pharmacies Is Putting Patients at Risk:*** https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html
  - ***At Walgreens, Complaints of Medication Errors Go Missing:*** https://www.nytimes.com/2020/02/21/health/pharmacies-prescription-errors.html
  - ***CVS, Walgreens and Walmart Fueled Opioid Crisis, Jury Finds:*** https://www.nytimes.com/2021/11/23/health/walmart-cvs-opioid-lawsuit-verdict.html
  - ***CVS Fined for Prescription Errors and Poor Staffing at Pharmacies:*** https://www.nytimes.com/2020/07/16/business/cvs-pharmacies-oklahoma.html
- Reddit subgroup R/Pharmacy and Accidental Pharmacist Facebook pages, #Pizzaisnotworking
  - Many voices in these groups that are crying out to be heard about current retail working conditions they are dealing with
- Recently published news articles about understaffing in light of additional responsibilities with Covid
- It is even worse now than my own experience over time in chains – 2012 – 2016, which led me to quit retail pharmacy and pursue other pharmacist work
- I will be eventually leaving the profession – feel abandoned and like no one cares about pharmacists or pharmacy – not pharmacy chains, not consumers, and not the Board of Pharmacy
- Was previously quite involved in mentoring pharmacy students and encouraging future pharmacists – will not be doing that anymore unless something changes
- Cannot continue to encourage a profession that does not care about its workers, who are merely working to serve the public as best as they can through their careers and to protect their safety
- Where are the Boards of Pharmacy?
  - Changes have been too slow, too late
  - Covid has significantly worsened situation
  - Where is the help for supposed “heroes” of healthcare who are most accessible healthcare professional to public???

Overview of This Document

- This document will address concerns at several levels with some proposed solutions
- I have sent this document to the NABP and to every state's Board of Pharmacy
- Chain pharmacies are managed on a national level
- Boards' approach to this problem should be coordinated national guidelines / action in addition to state-specific approaches to protect public health in each state and across nation
  - Utilize NABP resources
- Protecting safe staffing ratios and safe working conditions for pharmacists and technicians will increase public safety
  - Empowering pharmacists and technicians will empower public health over profits
  - Current business model of pharmacy does not incentivize public health over profits, other than intimidating licensees through punitive license-level discipline against working pharmacists, perpetuating fear, lack of reporting from pharmacists about unsafe working conditions in order to keep their licenses and livelihoods

Issue #1: Lack of Error Rate Transparency

- Chain pharmacies consider their error reports to be “trade secrets”
- Error rates are not shared with Boards of Pharmacy or public
- Public therefore is unaware of error rates at any pharmacy and is not empowered to choose a pharmacy that has a low error rate and is safer for them to fill prescriptions at
- Error rates at pharmacies do not affect insurance plan networks or reimbursement rates
  - Vs. other healthcare services do have quality components and financial incentives so that physicians prioritize quality of care over profits
- In practice, errors are pinned on individual licensees, and it is not acceptable to list staffing conditions or time pressures as factors or root causes in these errors
  - Disciplining based on errors should not stop at individual licensee – pharmacy chain and location needs to be held accountable for any working conditions that inherently increase risk of licensee making an error in first place
- Medication errors are costly and contribute to patient morbidity and mortality
  - insurance companies have financial and quality of care incentives to support and pay for retail pharmacists’ role in catching errors
- Proposed solution: Make error rates at individual pharmacy locations + aggregate chains publicly available and posted at locations so public has easy access to info to make informed decision on where to fill their prescriptions

Issue #1, con't: Lack of Error Rate Transparency

Proposed solutions, con't:

Make error rates at individual pharmacy locations + aggregate chains publicly available and posted at locations so public has easy access to info to make informed decision on where to fill their prescriptions

- Example: Similar to Food Safety and Inspection Services at restaurants and posting of a grade so the public is aware of how well the restaurant is following public health guidelines, such as proper food storage, hand-washing, etc.
- Example: Yelp-type anonymous reviews by public and staff on perception of safety / quality of care at individual pharmacies
- Funding can come from pharmacy site license fees and/or insurance companies (costly to have medication errors affect patients with their plans)
- Require error reporting at store / chain level AND to BOP – could be 2 separate processes; BOP process req'd by pharm law
  - Could also have a % error rate cut-off where, if store / chain has above x number or % error rate and/or among certain types of errors, MUST report this to BOP (thus, shielding BOP from having to deal with low error rates that may not be of public health concern, i.e. minor typing error vs. wrong drug dispensing that caused patient harm)
- Require store / chain response about changes they have undertaken to resolve error trends that are tied to their locations
- Incentive for insurances to include / exclude chains / pharmacy locations based on good vs. bad error rates
  - Could tie increased payments to high quality clinical services and/or factor into preferred pharmacy network selection
  - ~ Medicare STAR ratings for Medicare Part D plans

Issue #2: Multitasking, Interruptions, Overwork

- Contrast chain pharmacies to inpatient med administration rooms where nurses are alone in silent room with lock on it, uninterrupted to focus on medication prep and dispensing to avoid errors
- Nurse alone in silent, locked med room with no interruptions Vs. local CVS or Walgreens: RPh is juggling at least 3-5 different things
  - I wore a headset so I could do more at once to get everything done with time pressure, and I knew this extreme multitasking was not safe but had to do it to keep up with metrics
- More pharmaceuticals to keep track of (example: insulin as ISMP high error medication and explosion of diff insulin-containing products in last 5 years; will increase error rates involving insulin because so many products now and difficult to distinguish, ie. Humulin R vs. Humulin R 500 vs. combination products in both)
  - Continued multitasking & metric pressures + continued level of interruptions will lead to increased errors because of increased number of Rx products to mix up

Proposed solutions:

- BOP regulations that close current gap between dispensing meds in med admin room and in retail chain pharmacy and promote dedicated, uninterrupted time for licensee to do their job as pharmacist
  - Ban performance metrics quotas (following recent CA BOP law)
  - CA BOP law: banning pharmacist from working alone without additional staff in pharmacy to work register (i.e. front end cashier, etc.)
  - Create regulations that ensure that verifying pharmacists have uninterrupted time to make sure right patient, right medication, right dose, right time
  - BOP create minimum labor requirements for pharmacists – i.e. pharmacists by law entitled to lunch break, breaks, etc.
    - Similar to FAA requirements for pilots (i.e. pilots have max consecutive fly time / schedule) and caps on MD trainee hours in residencies to ensure that trainees are not working without sleeping, etc.
    - Create similar protective regulation to ensure that pharmacists are mentally present in order to verify prescriptions accurately, lower error rate, and protect public health

Issue #2, con't: Multitasking, Interruptions, Overwork

Proposed solution examples:

- Example regulation: require pharmacist overlap for certain number of hours every day during pharmacy hours – 1 RPh in corner, blocked off and free from interruption
  - Hypothesis: this will also increase productivity and safety, thereby being a triple win for RPh, retail chain, and public + insurance companies that are paying for morbidity and mortality related to drug errors in their members
- Example regulation: must be a dedicated patient consultation pharmacist on duty at all times
  - Main duty of this pharmacist is to counsel patients and/or provide MTM / med rec services
  - This pharmacist does not dispense unless there is no one available to counsel
- Example regulation: ban pharmacists and/or technicians from working register and/or have limits on how many technicians per day have to work register
  - Will force pharmacy chains to staff retail cashiers on pharmacy registers and allow tech and RPH licensees to focus on pharmacy-related duties and not on store duties that can be performed by anyone
    - Win for retail chains: will allow less costly hourly workers to ring patients up and will focus / increase volume of licensee activity that is specific to pharmacy

Issue #3: Current Disciplinary Action Does Not Look Beyond Individual Licensee or At Working Conditions

- Seems as though much of BOP disciplinary action stops at the licensee level; very punitive on individual level
  - Counter to principles of root cause error analysis and addressing errors – need to focus beyond the licensee and individual error and look beyond at the system-wide issues that are creating errors in pharmacies by licensees
  - Hypothesis: high error rates and disciplinary actions are a symptom of poor working conditions that can be addressed at store / chain level
- BOP is known for punitive license discipline – where is positive feedback and highlighting to licensees AND public of pharmacists who are preventing comorbidities, promoting patient health, and saving lives?
- Can look up disciplinary action against individual licensee, but what about against pharmacy location license?

Proposed solutions:

- Record, tally, and classify all individual licensee errors, pharmacies and chains at which errors occurred, trends among errors
  - Remove individual licensee error specifics
  - BOP should already have this data over long period of time → able to compile and analyze today
  - Identify outliers in region – plays into error rate transparency
- Solicit public's input on perception of safety / staffing at their local pharmacies
  - Receipt surveys at pharmacies?
  - Add to current public complaint reporting infrastructure
  - Create a BOP complaint response flow at pharmacy / store level in addition to exploring any individual licensee complaints – could Put BOP complaint information on Rx receipts to increase chance of public engagement in providing feedback about pharmacy experience; Similar to Press Ganey in MD world now; do Press Ganey-like surveys for pharmacy chains

Issue #3, con't: Current Disciplinary Action Does Not Look Beyond Individual Licensee or At Working Conditions

Proposed Solutions, con't:

- Rank chains and pharmacies by their relative error rate
  - Similar to suggestions for Issue #1, but use BOP data gathered without relying on chains releasing error rate information
- Publish this information publicly on BOP website and in newsletters ASAP
- Create a report using this information to analyze trends from previous years and investigate impact of staffing cuts over the past 10-15 years
  - Hypothesis: will see trend of increase in disciplinary action and consumer complaints over time as staffing hours have been slashed
- Require chains to report to the Board the store- and chain-level solutions that are being put into place to lower the quantity of disciplinary actions tied to them
  - Continuous feedback loop between BOP and chain pharmacies / pharmacy locations to promote continuous improvement in working conditions / error prevention at a chain and pharmacy level
- BOP visits and assessment of compliance to have component that assesses pharmacy staffing structure and total hours of pharmacists and techs working vs. workload / prescription volume and staffing trends over time
- Create a way that is easy for patients to check pharmacy location and any license discipline at pharmacy license level in addition to discipline against pharmacist licensees
- Create safety / quality metrics as part of assessment of pharmacy license renewal process
  - Can help focus away from dispensing errors and assess other healthcare quality and safety metrics at a store / pharmacy / regional level
  - Gradations of safety and quality metrics that would make pharmacy location license in jeopardy / on probation, etc.

Issue #4: Conflicts of Interest on Board of Pharmacy

- Pharmacists who sit on state boards are often in management for chain, encouraged by chain to sit on BOP
- If paid by their companies while sitting on board, clear conflict of interest
- Pharmacists who are in management and have been for years are too far from the realities of working on the front lines, often unaware of the direct impact and stress of staffing cutbacks because they are sitting in an office and not experiencing the extreme time and staffing pressure directly like a staff pharmacist working at a store daily is
- Pharmacists are afraid to report concerns to BOP because of retaliation potential with management on Board
- Pharmacists at front lines' general consensus that BOP members are out of touch with that space

Proposed solutions:

- Consider funding Board positions should be paid out of state general funds during pharmacist terms (unsure of how this currently works – need improvement on BOP salary transparency)
    - Transition to full-time position with salary paid by Board
- Place a limit as to the percent or number of pharmacist board seats that can be filled by pharmacy managers who work at chain pharmacies
- Require a minimum number of staff pharmacists on board seats who are not in upper management and are working daily on the front lines

Issue #4, con't: Conflicts of Interest on Board of Pharmacy

Proposed solutions, con't:

- Require BOP members to staff at local chain pharmacies x number of hours per month during their BOP terms
  - Similar to how IPPE / APPE hours are requirement to be licensed as pharmacist, need to have x number of staffing hours in order to maintain BOP term
- For community and retail representation, require a balance of which chains are represented at the table for more balanced decision making that prioritizes patients and public health
- Board of Pharmacy subcommittees that meet in different state regions / gather together pharmacist licensees in the area to offer feedback and suggestions
  - Subcommittee representation based on population of regions in state; try to have x pharmacists per 10,000 consumers / patients in area, etc.
- More anonymous surveys to chain pharmacists in particular on national and state level – should have pulse on working conditions and constant communication loop between BOP and licensees
  - Can tailor surveys to gauge implementation of new regulations in the field without relying on whistleblowers to come forward before action taken / identify lack of adherence by chains to new pharmacy regulations
- Before instituting any new BOP regulation, build in step where actively solicit state RPh input via anonymous surveys that are sent out via mail / email, etc.
  - Consider requiring a quorum from licensees via these surveys (could require participation as part of license maintenance) before instituting changes
  - Require pharmacist voting participation as part of license maintenance / renewal
    - i.e. as CE requirement: must vote on x percentage of BOP surveys / polls, etc.
- BOP should be actively reaching out to its constituents and licensees and not relying on them to go to website on own to report or comment

Issue #5: Conflicts of Interest in Retail Chain Pharmacy Management

- Hierarchy at chain pharmacies usually has pharmacist licensee as a subordinate to store manager or district manager
  - Store / district manager may or may not be a licensed technician
  - Store / district manager may have minimum high school GED education
  - Huge gap in educational background and understanding between pharmacists and their superiors
    - Creates inherent conflict and focus on business / profits / "customer service" over public health
- Non-pharmacists do not and will never understand corresponding responsibilities to report (i.e. child and elder abuse, etc.), pharmacist duties, and pharmacy laws like a licensed pharmacist, subtler gray areas of pharmacy practice and req'd pharmacist judgment
- Conflict between losing / gaining customers and providing due diligence for controlled substances
- Conflict between profits / prioritizing quantity over quality when RPh's are managed by people with business training but no RPh license

Proposed solutions:

- Require pharmacists to manage pharmacists at every level of retail chains, from district level to C-suite management
- Similar to requiring a CMO – Chief Medical Officer, what about a CPO – Chief Pharmacy Officer for all pharmacy-centric businesses
- MDs also do not have the same perspective as RPh – should be both MD and RPh partnership in pharmacy / health industry
- Cannot have non-pharmacist individuals manage pharmacists – not in public's best interest when business prioritize profits over health of public
- Require that chain drug stores employ a pharmacist error prevention / CQI pharmacist
  - Can require x number of error specialty pharmacist per x number of stores in regions
  - Potential to create additional certifications and payment for this type of pharmacy practice

Issue #6: Low Licensee Engagement with Boards of Pharmacy

- Pharmacists are overworked and beat down, work weekends and evenings with little control over their schedules at retail chains
- No incentive to attend BOP meetings in free time unpaid
- BOP is usually in state capitol during business hours, meetings not easily accessible by licensees who live and work far from the capitol
- Current licensees do not see how BOPs are taking action to assist with their complaints about workplace conditions and public safety concerns
- Current licensees see BOP only interested in consumer-level complaints against licensees, but what about pharmacist / technician complaints against pharmacy license holders (i.e. chain drug stores)

Proposed solutions:

- Virtual BOP meetings
  - Meetings outside of M-F 9-5 business hours – weekends and evening meetings; rotate days of week, and scheduled times for meetings
  - BOP increases actively reaching out to solicit participation and feedback from licensees to make it as easy as possible for licensee to engage with Boards

Issue #6, con't: Low Licensee Engagement with Boards of Pharmacy

Proposed solutions, con't:

- BOP members should travel around their states throughout the year
  - Increase engagement
  - Increase representation of licensees in different regions
- As part of CE req'ts / license maintenance, require minimum number of BOP meetings to attend in order to maintain licensure
  - Idea: stagger requirement like jury duty for RPh licensee duty
- Require pharmacy employers to pay for employee to attend any required BOP meetings as part of license maintenance, inc transportation costs and time in that
  - PTO day specifically for BOP meeting attendance
- Create regional subcommittees that can report to state BOP and meet locally
- More anonymous surveys that protect and encourage licensees to tell BOP true workplace conditions issues and feel safe from retaliation + feel supported that BOP will address these items on structural level
- Create BOP retail pharmacy safety / interest subcommittees to focus on concerns in retail pharmacy space
- Complaint hotline / path for licensed pharmacists and technicians to provide complaints about chain drug store locations and working conditions
  - Same / similar type of investigation and resolution pathway can be built for this that mimics current patient complaint process

Issue #7: Lack of Public Awareness / Knowledge About Role of Pharmacist

- General public has little to no knowledge about role of pharmacist
  - Even many licensed pharm techs do not know RPh educational background or medical knowledge base
  - General public sees pharmacists as a barrier to them getting their medicine vs. a partner in their health and guardian of their safety
  - General public cannot distinguish between technician and pharmacist duties, doesn't know difference between a pharmacist and a retail cashier, other than that pharmacists count pills and answer questions when asked
  - Drive through gives general public sense that we are more like a fast-food place than a doctor office
    - What medical service has any drive-throughs? None – medical services require more time and thought than drive-through fast food order
- Commonly posted BOP posters at pharmacy are not enough – consumers do not read them
  - Education about how pharmacists can help patients needs to go beyond the walls of the pharmacy
  - Too many posters taped everywhere – dilutes the message and decreases consumer interest / attention / understanding

Issue #7, con't: Lack of Public Awareness / Knowledge About Role of Pharmacist

Proposed Solutions:

- Public health marketing to increase general public's awareness of pharmacy
  - Advertisements: TV, newspapers, radio, pt mailings through insurance companies, required leaflet to give when dispensing Rx's, etc.
- Public health marketing to educate consumers on the wealth of information available to pharmacist
  - Commercials where OTC recommendation saves urgent care visit / copay, etc.; asking about side effects prevents ER / doctor visit (and saves patient copay)
    - Ex: dizziness thought to be related to meds – RPh can offer BP check and look at med list, then see that BP too low, rec to stop BP med and fax MD
- Suggested initial message: "Protect yourself: Check your prescriptions every time you pick up and talk to your pharmacist"
- Better marketing and distinguishing of pharmacists from technicians and cashiers in retail space
  - separate kiosk stations for pharmacists?
  - Public education as to what pharmacist white coat means
- Put BOP outreach information on receipts in pharmacies / where Rx's are dispensed and rang up
- More marketing about positive and preventive interventions that pharmacists perform every day – prevent / catch drug interactions, wrong dosing, maximizing medication therapies for patients, saving patients money, etc.

Issue #8: Lack of Payment for Pharmacist Clinical Services Not Tied to Dispensing Rx

- Outdated reimbursement model for pharmacists – still tied to dispensing as main revenue stream for pharmacies and will continue to perpetuate profit over public health until changed and until there are dollars tied to clinical services that protect public health and decrease errors / hospital or ER admissions
- Most of business profit / sales related to pharmacy directly tied to dispensing a prescription
  - This is what drives the quantity over quality – no profit tied to quality or error rate performance
    - Not in line with current trends in healthcare services – CMS STARS, HEDIS quality performance metrics and payments to health plans and providers based on quality
    - Where is this in pharmacy world?

Proposed solutions:

- Provider status to ensure pharmacists can bill for services, such as consultation time
  - Patient consultations increase public understanding of health and medicine, decrease ER and urgent care utilization, prevent hospitalizations, etc. – these are huge savings. Where is $ going to pharmacists for credit on these savings to insurance companies?

Issue #8, con't: Lack of Payment for Pharmacist Clinical Services Not Tied to Dispensing Rx

Proposed solutions, con't:

- Create additional outpatient services at pharmacy locations that can be billed through insurance companies, ~pharmacist provider clinical consultation
  - Higher payments for MTM services
  - MTM services as standard service covered by insurance plans that patients can request PRN
  - Medication reconciliation in outpatient setting
    - Similar to MTM services, patients can bring in hospital discharge paperwork and consult with pharmacist
    - PCPs bill insurances for these med reviews – revenue stream that can be redirected to pharmacies and pharmacists
    - Another triple win for pharmacy chain, pharmacist, and public health
    - Transition of care errors are expensive and cost a lot of money – insurance companies have skin in the game and incentive to pay for these services
  - Most of chains already have a PBM / insurance company affiliation (i.e. Walgreens and CVS Caremark) – revenue stream is already there, just not flowing to outpatient pharmacy
- Should be more clinical things related to vaccination / testing using Covid example
- Facilitate venue for payment to reward the # of errors prevented / "near misses" caught by CQI
- Can build pathways to create MD-supported / oversight of clinical services such as MTM or Med rec at pharmacy level (similar idea to protocols for OTC birth control dispensing, BP monitoring, PREP, vaccinations, etc.)

Issue #9: Board of Pharmacy Lack of Funding and Understaffing

- BOPs generally funded by state taxes
  - Taxpayers and public do not understand role of pharmacists or BOP
  - Generally, people do not see value in paying more taxes to support BOP functions
  - Chronic underfunding and understaffing of BOP
  - BOP not available to address licensee concerns in effective way
- Proposed Solution:
  - Find additional income streams to support BOP, even beyond licensee fees
    - Ex: increase pharmacy license fees, esp. seeing as chain pharmacy companies are making billions of dollars in annual profit – they can afford an increase in pharmacy license fees more than individual licensees can afford another increase in license renewal fees

Issue #10: Saturation of Pharmacy Space and Decreasing Pay

- Despite "pharmacy worker shortage" due to shortage of licensees who are willing to work in stressful, poor working conditions that do not support pharmacists' rights but support cutting corners to increase profits, there are ever expanding number of pharmacy schools and pharmacists graduating each year
- Pharmacist space is getting saturated
- More pharmacists and more schools → decreased value of licensees in eyes of retail chains and decreased pay when job is getting more complex
- Level of pay and demand of pharmacists by retail chains does not match risks of working to individual's license (pressure to fill and increase rate of error because of working conditions and increase risk of BOP disciplinary action / consumer complaints due to inherent increased error risk + lower pay for increasingly complex job with flood of new Rx products)
- Lowering incentive to attend pharmacy school and become a pharmacist / technician
  - Pay is approaching careers with much less personal liability and risk / level of potential harm to patients if make error

Proposed solutions:

- BOP have some teeth / role in limiting number of pharmacy schools and / or number of pharmacists who are licensed per year
- Cap on licensees or number of schools in each state (can be adjusted to per population basis) will create competitive space where only the highest qualified / performing licensees will be able to practice
  - Hypothesis: trickle down in patient quality of care and quality of clinical services provided by licensees in retail space

Possible Resources and Partnerships

Errors and Error Reporting, Consulting:

- ISMP

Professional Practice Changes:

- NABP to assist pharmacy boards in learning about other states' initiatives to respond to licensee complaints
- This is a national and not just a state-specific problem
  - Evident through news articles and pharmacist feedback from multiple states
- NABP should pool all states' BOP licensee complaints that are coming in, provide analysis of types of complaints at national level
  - Then each state can determine how they would like to address these issues in their states, but informed by national data
- NABP summary of diff states' BOP actions to attempt to address these practice issues

1/6/22

Attention Alaska Board of Pharmacy:

I am the Regional Pharmacy Director for PharMerica Pharmacies located in the Northwest. My company's pharmacy located in Vancouver WA (AK Pharmacy license #148356) currently services Prestige Care & Rehabilitiation Center located in Anchorage, Alaska.

This letter is to request authorization to place a Cubex RxNow machine into this skilled nursing facility, Prestige Care & Rehabiliation Center. A Cubex RxNow machine is an electronic eKit which also can function as a first dose kit. An electronic emergency drug kit enables the facility to securely maintain on site an inventory of medication only accessible to authorized facilitiy staff who have a valid prescription order for the resident. Controlled substance cannot be accessed without a validation code provided by the pharmacist. The inventory will be maintained by our pharmacy. Some of the advantages of using a Cubex over a manual eKit or manaul first does kit include the following:

- inventory is securely maintained
- inventory levels can be check electronically by the pharmacy or the nursing staff
- all transactions are electronically recorded by user using fingerprint technology
- controlled substances can only be accessed by a code issued by the pharmacist to the authorized facility staff when a qualified new unused prescription is available for the resident
- dispensings are updated electronically to the patient's pharmacy medication record

I have enclosed a copy of the Cubex machine user guides as well as a copy of our policies and procedures we wil be following to maintain inventory and security of the machine.

In addition if approved the Cubex machine will be operated and maintained in accordance with the rules found in 12 AAC 52.830 and 12 AAC 52.840.

Thank you,

Keith Koscielski RPH

Alaska Pharmacist License # 144147

Emergency Medications Policy

Policy Reference

Emergency Drug Kit (EDK) Policy and / or Automated Dispensing Systems (ADS) Policy.

Applicable To

- Long Term Care Pharmacy

Functional Role(s) Responsible

- Regional Pharmacy Directors
- Pharmacy Directors

Corporate Resource

- Compliance Department

References

- Policies for Emergency Drug Kits (EDK) and/or Automated Dispensing Systems (ADS) units will provide in greater detail of individual policy sections.

Purpose

To highlight the broad requirement of emergent resident medication needs, and to ensure that the pharmacy has adequate inventories of emergency medication available meet these needs.

Policy

The pharmacy, in conjunction with the long-term care facility, will have adequate inventories of emergency medications available to meet the needs of the residents. When applicable, based on state and federal guidelines, the pharmacy and long-term care facility will develop a list of emergency medications based on need at the long-term care facility. This policy is intended to highlight the broad requirement of emergency medication needs.

Procedures

- The pharmacy and facility will approve Emergency Drug Kit (EDK) or Automated Dispensing System (ADS) formulary or content listing.
- The EDK/ADS formulary is maintained by the pharmacy and facility administration.
- Any modifications or changes require the pharmacy director and facility leadership to approve prior to implementation.
- The medications are kept secure in and (EDK) or ADS according to state standards
- The medications are checked prior to dispensing for correct medication, quantity, integrity, expiration dates according to PharMerica KPI.
- Emergency use is documented and retained by the facility and pharmacy.

- PharMerica approved EDK Utilization form is filled out to completion and faxed to pharmacy after each pull.
- One copy of the EDK Utilization form is retained at the facility, and one placed back in EDK for pharmacy documentation.
- Document authorization code is provided by pharmacist for all controlled medications on each EDK utilization form.
- When reconciling a returned EDK, any missing medications (without patient information) MUST be reported to the Pharmacy Director, and may be billed to house account.
- The pharmacy will ensure a system is developed to retrieve and recall information about each EDK and record. The PharMerica KPI, Core Process further defines the EDK requirements. Furthermore, the ADS policy and procedure addresses policy and guidelines for emergent ADS utilization.
- Physician orders are reviewed by a pharmacist for appropriate use.
- Emergency medications are only administered after a valid physician's order.
- Control Substances are removed only after a valid authorization code from the pharmacist is given and documented.

Additional RxNow Machine Guidance to support separate ADS policy

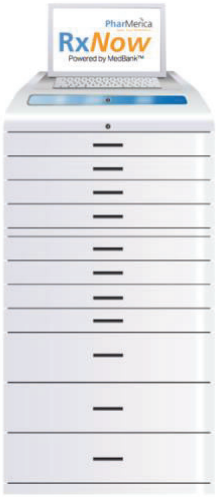
- Ensure all applicable state and federal guidance on utilization and restocking is adhered to.
- Define who is to replenish ADS units (nurse, RPH, CFS, Tech)
- Review the previous day's billing report daily for medication removals.
- Verify that all controlled medications link to a valid script and pharmacist authorization code.
- Verify that removals match billing.
- Once a week (or more frequent for high moving ADS) review medication below minimum report and replenish as needed.
- Once a month review Expiring Medications report to validate dating and replace as needed.

PharMerica

RxNow

Powered by MedBank™

Solution Quick Reference Guide



Customer Support
8[illegible]251
support@[illegible]com

Who We Are

PharMerica has partnered with Cubex LLC MedBank Solutions, a global provider of health care solutions and services that measurably improve the availability of first dose and emergency medications while reducing the total cost of ownership associated with medication management.

RxNow Solutions powered by MedBank exist of automated dispensing cabinets, wireless access devices and the cloud-hosted myQLink software application that together improve the overall performance of the supply chain while providing the data you require to make better informed business decisions.

RxNow Solutions:

- Reduce stat and back-up deliveries
- Automate manual reorder processes
- Integrate with EMR systems
- Improve regulatory compliance through high security, unit dose dispensing
- Allow staff more time to focus on patient care

Contact Us

We are here for you! For questions or further assistance, please contact Cubex LLC MedBank Solutions Customer Support at:

Phone 1.866.930.9251 U.S. & Canada
Opt. 1: Customer Support

Email support@cubex.com (Response within 24 hours)

Chat Via myQLink.biz http://www.myqlink.biz (Admins only)via Internet portal www.cubex.com/customerportal

Web To access release notes on software and other resources www.cubex.com/customerportal

1. **Log in** using your credentials
2. **Search** for and **Select** the desired patient using first or last name to narrow the patient list
3. Press **Issue/Return/Waste** to access patient's profile
4. Select item(s) to be issued, ensuring item box is check marked on the left
    - If the item(s) doesn't appear on the profile and user permissions allow, press **Add Item(s)** to add an item to the patient's profile
5. Enter the desired dose in the highlighted **Qty** column
6. Press **Issue Item(s)**, the drawer and or CUBIE containing the selected item will open
7. Remove the desired dose from the bin or CUBIE
8. Complete the current transaction by closing the CUBIE and or drawer and press **Next**
9. Repeat steps 7 & 8 until all selected items are issued
10. Press **Exit** to log out when completed with transaction(s)

Issue Item to a Profile Patient

1. **Log in** using your credentials
2. **Search** for and **Select** the desired patient using first or last name to narrow the patient list
3. Press **Issue/Return/Waste**
4. Press **Return** to display items available for return
5. Select the item to be returned
6. Press **Select Item**
7. Enter the **Return Dose** quantity
   (Note the Unit of Issue – ml, vial, tab, etc.)
8. Press **Next**
9. Press **Add Items** (if applicable) to add items to the list or select **Return Items Now**
10. The drawer and or CUBIE containing the selected item will open
11. Place the desired dose into the bin or CUBIE
12. Complete the current transaction by closing the CUBIE and or drawer and press **Next**
13. Press **Exit** to log out when completed with transaction(s)

Item Return

1. **Log in** using your credentials
2. Press **Admin**

You have the option to **re-fingerprint** or **change PIN**

Re-Fingerprint

3. Use the fingerprint scanner to scan the desired finger
    - The first scanned print will appear on the display once it has been accepted
    - Lift the finger and repeat 2 or 3 more times (depending on scanner) with the same finger
    - Enrollment is now complete

Change PIN

4. Enter new PIN, confirm PIN, and select Change PIN
    - You should see a "PIN changed successfully" message in white lettering appear
5. Press **Back** or **Exit** when complete

1. **Log in** using your credentials
2. Press **Add Patient**
3. Enter all required information indicated with an * and additional fields, as instructed by your System Administrator
4. Press **Add Another Patient**, (if applicable), or
5. Press **Issue/Return** to add this new patient to the patient list and to access the patient's blank profile

Add New Patient

1. **Log in** using your credentials
2. Press **Restock**
3. Press **Scan Barcode** (if applicable)
4. Scan the replacement/new CUBIE bar code and press **Next**
5. The CUBIE drawer will open
6. For CUBIE replacements:
    - The CUBIE being replaced will release itself from the drawer
    - Remove the released CUBIE from drawer and secure the replacement CUBIE in that same location

    (Removed CUBIEs must be sent back to pharmacy)
7. For New CUBIEs (new item(s) being added):
    - Find an opening large enough for the scanned CUBIE and secure it into place
8. A confirmation screen will appear displaying all pertinent info (description, max/min, quantity stocked, expiration date, etc.) regarding the medication
9. Complete the current transaction on the screen by pressing **Next**
10. Repeat steps 4 thru 9 for any additional CUBIEs
11. Press **Exit** to log out when completed with transaction(s)

Restock (CUBIEs with barcodes)

1. **Log in** using your credentials
2. Press **Restock**
3. Press **Scan Barcode** (if applicable)
4. Scan the replacement/new item bar code and press **Next**
5. The drawer with the scanned item will open or the screen will direct you to the External location
6. For Matrix and Extremal item replacements:
    - Add the replacement item to the corresponding bin location
    - Edit the expiration date to the earliest date in the selected bin location
7. Complete the current transaction on the screen by closing the drawer (if applicable) and pressing **Next**
8. Repeat steps 4 thru 7 for any additional items
9. Press **Exit** to log out when completed with transaction(s)

Restock (Matrix/External items with barcodes)

PharMerica
RxNow
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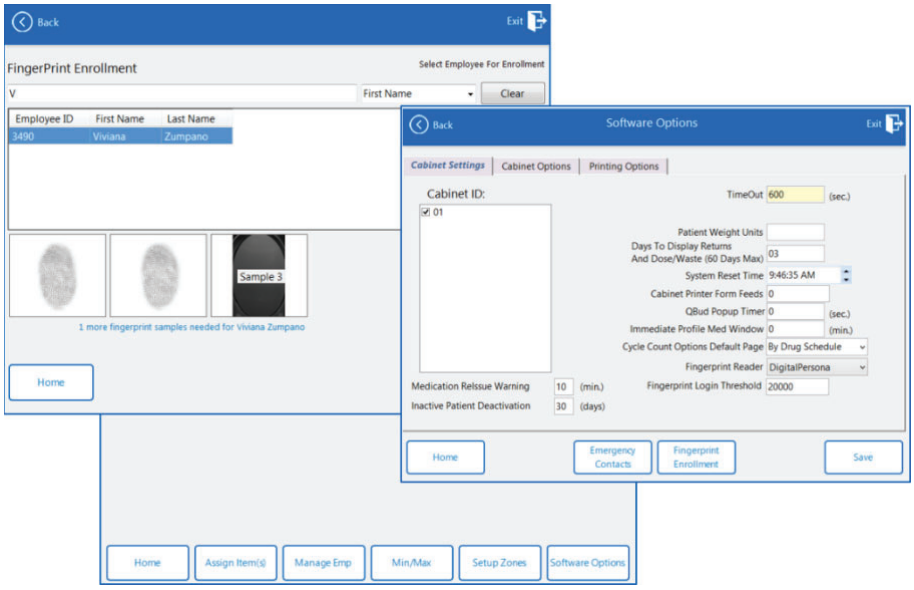

Please refer to the Customer Portal
www.cubex.com/customerportal
for reference guides, videos,
and additional supporting material.

1. **Log in** using your credentials
2. Press **Admin**
3. Press **Software Options** and then press **Fingerprint Enrollment**
4. Search for the employee's name (default search is by First Name) by typing in the search field, then select the desired employee when found
5. Use the fingerprint scanner to scan the desired finger
    a. The first scanned print will appear on the display once it has been accepted
    b. Lift the finger and repeat 2 or 3 more times (depending on scanner) with the same finger
    c. Enrollment is now complete
6. Press **Exit** when complete

If the user wants to change PIN or Fingerprint, they can do so once logged in by selecting **Admin**

Employee Fingerprint Enrollment (Admin)

You can save your Cycle Count preference by pressing the Save Default button after your preferences have been selected. Once that is completed, those preferences will be the default Cycle Count every time you sign in!

1. **Log in** using your credentials
2. Press **Cycle Count**
3. Press **Options** or **External**
4. Select to see items by Drug Schedule, by Zone, or by Item List
5. Select your item(s) or parameters
    - Place a ✓ in the Select box for the entire Zone, Drug Schedule, or specific item
    - Place a ✓ in the "Select Items accessed since last Cycle Count" column for a quicker count on groups of items
6. Press **Next**
7. The drawer and or CUBIE containing the selected item(s) will open individually
8. Physically count the selected item and type this quantity into the **Found** field
9. Press **Next** to complete the transaction or continue to the next selected item(s)
10. Press **Exit** to log out when completed with transaction(s)

1. **Log in** using your credentials
2. Press **Cycle Count**
3. Press **Destock Expiring Meds**
4. Enter desired parameter in the **Days to Look Ahead for Possible Expiration** field
    - The date field on the far right will automatically adjust to the calendar date you're looking out to.
    - A negative value in the Days to Expiration field will indicate a medication already past its expiration date.
5. Select the item(s) by placing a ✓ in the left-hand column or in the Select All field at the top of the screen to select every item.
6. Press **Next**
7. The drawer and or CUBIE for the selected item(s) will open
8. Physically count the selected item and enter this quantity into the **Found** Field
9. Enter the desired quantity to remove into the **Quantity Removed to Expired Waste** Field
10. Remove the expired product
11. Update the **Soonest Expiration Date** field
12. Complete the current transaction by closing the CUBIE and or Drawer and press **Next**
13. Press **Exit** to log out when completed with transaction(s)

Destock Expiring Meds

1. **Log in** using your credentials
2. Press **Admin** then press **Assign/De-Assign**
3. Press **Non-Button Items** for items in a Matrix or CUBIE drawer
    - Select the Device (desired drawer)
    - Search for and select the item to assign
    - Press **Add>>**, to add the item to the assign list
4. Press **External Items** for items outside of the RxNow
    - Follow steps b thru c listed above
5. Press **Next**
6. Place the item in the assigned location
7. Enter the required information (e.g., Max, Min, Critical Level (if applicable), Quantity Stocked, Expiration Date, etc.) in the fields provided
8. Press **Next**
9. Repeat steps 3 thru 8 for additional items
10. Press **Exit** to log out when completed with transaction(s)

Assign Items

1. **Log in** using your credentials
2. Press **Admin** then press **Assign/De-Assign**
3. Press **Non-Button Items** for items in a Matrix or CUBIE drawer
    a. Press **De-Assign**
    b. Search for and select the item to de-assign
    c. Press **De-Assign Item**
    d. The drawer and or CUBIE containing the selected item will open, remove the item
    e. Press **Yes** on the pop-up message to confirm
4. Press **External Items** for items outside of the RxNow
    a. Press **De-Assign**
    b. Search for and select the item to de-assign
    c. Press **OK** to de-assign selected item
    d. Remove selected item from previous assignment location
    e. Press **Cancel** to go back to the previous screen
5. Repeat steps 3 thru 5 for additional items
6. Press **Exit** to log out when completed with transaction(s)

De-Assign Items

1. **Log in** using your credentials
2. Press **Admin** then press **Manage Emp**
3. Search for and Select the desired user profile or Template to create a new user from
4. Press **Copy**
5. Enter all required information marked with an *
    a. Employee ID and Cabinet Login ID will be the same
        i. Initials of first and last name plus the last four digits of their social security #
            1. John Doe = JD9876
    b. PIN will be the password used to log in manually along with the Login ID
6. Press **Add Employee**
7. Repeat steps 3 thru 6 for additional users
8. Follow the *Admin Employee Fingerprint Enrollment* instructions to establish the users fingerprint
9. Press **Exit** to log out when completed

If the user wants to change PIN or Fingerprint, they can do so once logged in by pressing **Admin**

Add New Employee

Inactivate an Employee

1. **Log in** using your credentials
2. Press **Admin** then press **Manage Emp**
3. Search for and Select the desired user profile
4. Press **Inactivate**
5. Press **Confirm Inactivation**
6. Repeat steps 3 thru 5 for additional users
7. Press **Exit** to log out when completed

Contact your Corporate Admin to re-activate a user's profile.

Modify an Employee

1. **Log in** using your credentials
2. Press **Admin** then press **Manage Emp**
3. Search for and Select the desired user profile
4. Press **Modify**
    a. Edit the Cabinet Login ID, PIN, or Email fields
5. Press **Confirm**
6. Repeat steps 3 thru 5 for additional users
7. Press **Exit** to log out when completed

1. **Log in** using your credentials
2. Press **Resolve Discrepancy**
3. Select the discrepancy (DI) to be resolved
    a. If needed, narrow the list of discrepancies by searching for a specific DI or selecting Open Discrepancies or those already Nurse Reviewed
4. Press **Resolve Discrepancy**
    a. The DI report showing 2 transactions prior to the found DI and, if available, 2 transactions after the DI will appear
5. From the **Select** drop-down, choose the reason for the DI
    a. Add additional text in the **Discrepancy Notes** field if needed
6. Press **Resolve Discrepancy**
7. Have a Witness enter their credentials (the user's credentials will be their login to the RxNow)
8. Press **Next**
9. Repeat steps 3 thru 8 until all desired DIs are resolved
10. Press **Exit** to log out when completed

11.5 RxNOW AUTOMATED MEDICATION CABINET SERVICES

1. Program Description. RxNow is an automated medication cabinet and software program (the "Cabinet") that provides immediate access to emergency and first-dose medications.
2. Pharmacy's Responsibilities. Pharmacy will:
   a. Provide Cabinet, router, and establish a secure virtual private network (VPN) connection.
   b. Provide access to Cabinet by creating users' accounts and consultative support on connectivity and technical infrastructure required for implementation of Cabinet.
   c. Provide delivery, training and technical support for Cabinet.
   d. Provide and restock inventory of medications for the Cabinet by type, number and quantity in Pharmacy's sole discretion and as allowed by Applicable Law.
3. Client's Responsibilities. Client will, or cause Customer to, as the case may be:
   a. Provide a standard 120 volt power outlet and power supply for the Cabinet at its own cost. It is recommended, but not required, to be on a generator backed up circuit.
   b. Provide access to the internet through a VPN connection and obtain a fixed IP address from its internet service provider.
   c. Provide a safe and secure location in the Customer's facility for the Cabinet that deters unauthorized access and safeguards PHI being viewed on the screen by unauthorized persons. Client shall be responsible for all costs associated with the replacement of stolen, lost or intentionally damaged inventory. Client shall allow and participate in a complete inventory of the Cabinet and its peripherals as requested by Pharmacy.
   d. Process and obtain all first-dose, STAT, and emergency eligible prescription fills through the Cabinet. For those medications available through the Cabinet at the time of an order, any request for a STAT or other special delivery not a part of the regularly scheduled delivery for Client shall, at Pharmacy's sole discretion, incur a charge of $250 plus the cost of the medication at the contracted rate.
   e. Where applicable, process drug destruction and drug returns using the Cabinet.
   f. Assist Pharmacy in restocking medications of the Cabinet in a manner consistent with Applicable Law.
   g. Participate in periodic user group meetings and product innovation advisory panels that will be held at mutually agreed upon times, not to exceed four (4) times per year.
   h. Participate in periodic marketing initiatives, such as customer testimonials and other related marketing campaigns.
   i. Assist Pharmacy in capturing metrics regarding the impact of the Cabinet on facility operations, reduction in costs, and quality improvement.

j. Utilize the Cabinet only in connection with Pharmacy's Services and Products during the term of the Pharmacy Services Agreement.

4. The Cabinet shall remain Pharmacy's exclusive property. Client shall not do anything to infringe upon Pharmacy's ownership rights in the Cabinet, including but not limited to, Pharmacy's intellectual property rights. Client shall not reverse engineer, disassemble or decompile any software or other tangible objects which are provided by Pharmacy hereunder.

5. With respect to the Cabinet, Client: (i) shall only use medications provided by the Pharmacy in the Cabinet or as expressly authorized by Pharmacy; (ii) is responsible for any loss of or damage to the Cabinet that occurs when the Cabinet is in its possession, including, but not limited to, any theft, vandalism, or other misuse; (iii) shall return the Cabinet to Pharmacy upon termination of this Agreement, for any reason, in substantially the same condition as it was on the date first provided to Client, with reasonable wear and tear taken into account; (iv) may not assert any ownership interest in the Cabinet; (v) shall cooperate with Pharmacy in the filing of, and hereby authorizes Pharmacy to so file, any Uniform Commercial Code financing statements or other filings requested by Pharmacy, to evidence that the Cabinet is owned by Pharmacy; and (vi) shall not allow any type of lien or claim to attach to Cabinet and will defend and indemnify Pharmacy from the same.

6. From time to time, Pharmacy may add functionality to the Cabinet that expands the breadth of the application beyond what is initially included. Pharmacy is not required to provide this expanded functionality to Client as part of the basic Cabinet functionality as these added functions may require additional hardware or software enhancements not presently available for the Cabinet provided.

7. The contents of the Cabinet shall remain the property of Pharmacy until properly dispensed to a patient. Once an item is removed from the Cabinet, the Client will be billed for the ingredient cost of the medication set forth in the pricing schedule of this Agreement. Any items returned to the Cabinet in a condition suitable for reuse, as determined solely by Pharmacy and as allowed by Applicable Law, shall be credited to Client.

   Client acknowledges and agrees that Pharmacy will incur upfront costs to procure an RxNow automated medicine cabinet. Therefore, if Client terminates the Agreement prior to three (3) years from date of implementation, Client shall pay Pharmacy as liquidated damages, and not as a penalty, a lump sum payment, to account for the remaining balance of the RxNow equipment fee, to be calculated by multiplying the monthly cost per Cabinet by the number of months remaining until the third (3) anniversary date of implementation.

8. LIMITATION OF WARRANTIES. PHARMACY EXCLUDES AND DISCLAIMS ALL EXPRESS, IMPLIED, OR STATUTORY WARRANTIES AND CONDITIONS NOT STATED HEREIN, INCLUDING ANY WARRANTIES OF MERCHANTABILITY. ALL WORK PRODUCT PREPARED BY PHARMACY OR WHICH IS PROVIDED TO CLIENT FOR INSTALLATION AND USE AT CLIENT'S FACILITIES IS PROVIDED ON AN "AS IS" AND "WHERE IS" BASIS, WITHOUT WARRANTY OF ANY KIND.

NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS SCHEDULE: (I) PHARMACY'S AGGREGATE LIABILITY IN CONNECTION WITH THIS SCHEDULE AND THE PROVISION OF SERVICES AND PRODUCTS UNDER THIS SCHEDULE, REGARDLESS OF THE FORM OF ACTION GIVING RISE TO SUCH LIABILITY (WHETHER IN CONTRACT, TORT, OR OTHERWISE), SHALL NOT EXCEED $10,000; AND (II) IN NO EVENT MAY PHARMACY BE LIABLE, WHETHER IN CONTRACT, IN TORT, OR UNDER ANY OTHER LEGAL THEORY, FOR ANY INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING ANY LOST DATA, LOST PROFITS, OR INJURY TO GOODWILL OR REPUTATION, ARISING FROM OR RELATING TO THIS SCHEDULE, EVEN IF PHARMACY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE. THE LIMITATIONS OF LIABILITY CONTAINED IN THIS SECTION AND ELSEWHERE IN THIS SCHEDULE ARE A FUNDAMENTAL PART OF THE BASIS OF THE PARTIES' BARGAIN HEREUNDER, AND THE PARTIES WOULD NOT HAVE ENTERED INTO THE AGREEMENT ABSENT SUCH LIMITATIONS.

From: Richard Holt
To: Carrillo, Laura N (CED)
Subject: Efficiency Considerations: MPJE
Date: Wednesday, December 8, 2021 12:55:10 AM

Good morning Laura and board members.

I know all of you are busy with work, life, and Covid. Thank you for your continuing dedication and contribution that you are making.

I had a topic related to pharmacist licensing for your consideration and that is the MPJE.

1) The following states use NABP to confirm the eligibility of an applicant to take the MPJE: Colorado, Kentucky, Maine, Michigan, Nebraska, Oregon, Rhode Island, and Utah. Is there any way Alaska can join this list and take that task off the AK board of pharmacy plate? They charge the candidate a fee for doing this. Could this help AK become more efficient?

2) Idaho is a recent state that completely eliminated MPJE and the applicant merely signs an affidavit as part of their application (page 5). I believe Arkansas and California also do **not** use MPJE; there may be others that I'm unaware of. This may be an area for the board to consider in the future. Is a law exam necessary? A pharmacist is responsible for all laws whether they get a 75 or any score higher. Is there a significant safety risk whether they get a 74? If there was no exam, they would be equally liable for following all laws anyway so at the end of the day is it necessary since it does not remove any responsibility from the practicing licensee?

In fact, AS 08.80.110 QUALIFICATIONS FOR LICENSURE BY EXAMINATION and AS 08.80.120 GRADING AND CONTENT OF EXAMINATION do **not** mention any law exam requirement in obtaining a license by examination. Only in AS 08.80.145 RECIPROCITY; LICENSE TRANSFER does it have a requirement for "...testing the knowledge of Alaska laws..."

Do practitioners have to take law exams? I did a quick search of the AK medical board and didn't see anything about a specific law exam pertinent to AK laws. If not, why do we stand out by requiring a law exam? The laws change with time anyway yet nobody takes an exam in 15 years to see if they know the current laws so I think this begs the question as to why is there an underlying necessity to pass an AK law exam one time? Does a one-time law exam enhance patient safety? Certainly I don't believe pharmacists in Idaho, where MPJE was discontinued, are putting their patients in jeopardy due to lack of a law exam.

Just a couple of thoughts for your consideration as you review and amend statutes and regulations.

Thank you,
Rich Holt
Pharmacist

From: Bruce, Maimuna
To: Carrillo, Laura N (CED)
Cc: Adams, Jessica (Regulatory Affairs)
Subject: Proposed Amendment - TP regulations
Date: Tuesday, January 11, 2022 8:00:14 AM
Attachments: image001.png
image002.png
AK Mileage amendment.docx

Hello Laura!

I hope you're having a good start to your work week. Thank you again for taking the time to speak with me last week. As promised, I'm attaching the proposed amendment my team and I produced. I believe it's straightforward but let me know if you have any questions or concerns.

Have a great week!

Maimuna Bruce-Uzzell, PharmD, MBA, MS
Manager, Regulatory Affairs, TelePharm
123 N Linn St Suite 2F, Iowa City, IA
847.887.4891 mobile

TelePharm is joining forces with OutcomesMTM™ and mscripts™ to form Outcomes™. Learn more here.

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12 AAC 52.423. REMOTE PHARMACY LICENSE.

(a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12 AAC 02.310; and

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

(1) it is able to comply with the requirements of 12 AAC 52.425; and

(2) ~~there is no access to a non-remote pharmacy within ten road miles of the proposed remote pharmacy site unless the non-remote pharmacy is prevented by federal law from providing pharmacy services to all the individuals within the ten road miles~~.

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY.

(a) Only a pharmacist employed by a central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist located in this state. The pharmacist-in-charge of a remote pharmacy may supervise one or more remote pharmacies.

(b) Before a pharmacist employed by a central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

(1) still image capture;

(2) real time link;

(3) store and forward.

(c) A remote pharmacy must be

(1) staffed by a pharmacist, pharmacy technician, or pharmacy intern; and

(2) operated under the direct supervision of a pharmacist.

(d) A remote pharmacy must be secured to prevent unauthorized access at all times when a pharmacist is not available to provide direct supervision to that location.

(e) Drugs may be shipped to a remote pharmacy from the central pharmacy or a wholesale distributor. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped.

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must have access to the records of the prescriptions dispensed by the remote pharmacy.

(g) The prescription label of a prescription drug dispensed by a remote pharmacy must meet the requirements of 12 AAC 52.480.

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the remote pharmacy. A prescription drug may not be dispensed by a remote pharmacy until a pharmacist employed by the central pharmacy has verified the finished prescription product through the telepharmacy system.

(i) A pharmacist must conduct a physical inventory at each remote pharmacy location at least annually. The record of the inventory must be

(1) kept both at the central pharmacy and the remote pharmacy; and

(2) distinguishable from the inventory of the central pharmacy and other remote pharmacies.

December 14, 2021

Dear State Medical and Pharmacy Boards,

On November 15, 2021, the modified Risk Evaluation and Mitigation (REMS) program for clozapine launched for health care professionals and patients. Shortly thereafter, FDA began receiving reports from stakeholders across the country about serious difficulties interacting with the program impeding patient access to the drug.

FDA takes these concerns very seriously. On November 19, 2021, to help address these challenges and avoid sudden interruptions in patient care, FDA announced that it would temporarily exercise enforcement discretion for certain requirements of the Clozapine REMS. During this period, **FDA does not intend to enforce certain provisions** of the Clozapine REMS:

Temporary Enforcement Discretion for Certain Clozapine REMS Requirements

REMS Stakeholder Role	REMS Requirement	Does enforcement discretion apply?	What does this mean for stakeholders
Pharmacies	Obtain a Request to Dispense Authorization (RDA) through the Clozapine Call Center	Yes	FDA does not intend to object if pharmacists dispense clozapine without obtaining an RDA.
Wholesalers	Confirm pharmacies and health care settings are enrolled in the REMS	Yes	FDA does not intend to object if wholesalers ship clozapine to pharmacies and health care settings without confirming enrollment in the REMS.

FDA believes that the decision not to enforce specific elements of the REMS on a temporary basis should alleviate any barriers for patient access to treatment resulting from call center wait times. Abrupt discontinuation of clozapine can result in significant complications for patients, and patient safety is our top priority.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We encourage pharmacists and prescribers to continue working with the Clozapine REMS to complete certification and patient enrollment. Prescribers and pharmacists should continue to monitor their patients' absolute neutrophil count (ANC) according to the FDA-approved labeling and report those values using the Patient Status Form when feasible to the Clozapine REMS program.

FDA is also aware of reports that some clozapine insurance claims have been rejected when RDAs are not provided during claim adjudication or submission. FDA is reaching out to payer groups to clarify that RDAs may not be consistently issued during this period of enforcement discretion, and encouraging insurance providers to develop an override code, if necessary, for rejected claims.

We will continue to provide updates on the status of the Clozapine REMS modification implementation as issues resolve with the program. If you have questions or concerns about the Clozapine REMS Program or its website, please contact FDA at druginfo@fda.hhs.gov, 1-855-543-3784 or 301-796-3400.

We hope this information is helpful. Please feel free to contact FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov if you have any questions. Thank you.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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NABP
National Association of Boards of Pharmacy

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Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – MPJE PARTICIPATING STATES, MPJE Item Writers, MPJE Review Committee

FROM: Maureen Garrity, Competency Assessment Director

DATE: January 6, 2022

RE: MPJE Item Development Workshop – March 9-11, 2022

The National Association of Boards of Pharmacy® (NABP®) will host the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Item Development Workshop on March 9-11, 2022, at NABP Headquarters in Mount Prospect, IL. The item development process is a collaborative effort, and NABP encourages all MPJE participating states to attend this important workshop.

The tentative meeting schedule is (all times are Central Daylight Time):

Wednesday, March 9: Arrive in Chicago, IL, by 2:45 PM and check in at the Hilton Chicago/Northbrook Hotel.

- Shuttle to NABP Headquarters in Mount Prospect
- Item training session 3:30 to 4:45 PM (Group dinner to follow)

Thursday, March 10: 8:30 AM to 4 PM item writing (Group dinner to follow)

Friday, March 11: 8:30 AM to 3 PM item writing

NABP will reimburse approved expenses (travel, food, and lodging) for up to two participants from each state to attend the workshop. However, NABP may need to limit the attendance from any jurisdiction to one participant in the event of space limitations. If your state board is unable to send a representative, the writing assignment will need to be completed remotely. Full details, including content areas to be targeted and logistics, will be provided at a later date to the designated item writers who will write remotely.

Please provide contact information on the response form for the individual(s) who will attend the workshop on site, or for those who will complete the state assignment remotely. The NABP Meeting Services department will forward travel and hotel information approximately six weeks prior to the meeting once NABP has secured the names of the attendees.

If you have any questions or comments, please contact Anne Woolridge, competency assessment supervising coordinator, at awoolridge@nabp.pharmacy or 847/391-4534, or me at mgarrity@nabp.pharmacy or 847/636-1674.

2022 MPJE Item Development Workshop

Please indicate your state's commitment to the 2022 MPJE Item Development Workshop assignment by indicating either attendance at the workshop taking place March 9-11, 2022 **or** remote participation. This form is in a fillable format. It requires Adobe Reader 6.0 or higher. Open the file, add the information, and click "yes" to save the changes. Please email this form to MPJE@nabp.pharmacy no later than **Monday, January 21, 2022.**

State Board:_____

☐ Attending the MPJE workshop at NABP Headquarters on March 9-11, 2022.

☐ NOT attending and will complete the assignment remotely.

MPJE Item Writer Contact Information

Please provide the contact information for the individuals who will attend the MPJE Item Development Workshop **or** will be completing the writing assignment remotely.

Item Writer:_____

Phone:_____

Email:_____

Item Writer:_____

Phone:_____

Email:_____

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Mount Prospect, IL 60056
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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey “Al” Carter, Executive Director/Secretary

DATE: December 16, 2021

RE: FDA Letter on Ivermectin

On December 13, 2021, the US Food and Drug Administration (FDA) issued a letter to NABP regarding drug products containing ivermectin, including compounded drug products, being offered for sale to treat or prevent Coronavirus Disease 2019 (COVID-19). The letter from FDA is attached.

Attachment

cc: NABP Executive Committee

December 13, 2021

Lemrey "Al" Carter, MS, PharmD, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Dr
Mount Prospect, IL 60056
acarter@NABP.pharmacy

Dear Dr. Carter:

The purpose of this letter is to bring to the attention of the National Association of Boards of Pharmacy information related to drug products containing ivermectin being offered for sale with claims that such products treat or prevent "Coronavirus Disease 2019" (COVID-19). Recently, FDA has received complaints about compounding pharmacies selling drug products containing ivermectin, claiming that they can treat or prevent COVID-19.

Ivermectin tablets are FDA-approved for humans at very specific doses to treat some parasitic worms, and there are FDA-approved topical (on the skin) formulations for head lice and skin conditions like rosacea. However, the FDA has neither authorized nor approved any ivermectin drug product for use in preventing or treating COVID-19. Although clinical trials assessing ivermectin tablets for the prevention or treatment of COVID-19 in people are ongoing, currently available data do not show that ivermectin is safe or effective for the prevention or treatment of COVID-19.

Additionally, as the agency has previously explained, there are many side effects associated with ivermectin, including skin rash, nausea, vomiting, diarrhea, stomach pain, facial or limb swelling, neurologic adverse events (dizziness, seizures, confusion), sudden drop in blood pressure, severe skin rash potentially requiring hospitalization and liver injury (hepatitis).

Using ivermectin products in preventing or treating COVID-19 may pose risks to patient health or lead to delays in getting effective treatment of COVID-19. Drug products that claim to treat or prevent COVID-19 but are not proven safe and effective for those purposes can place consumers at risk of serious harm.

We are also sending this letter to the Federation of State Medical Boards to facilitate communication among associations with shared goals regarding these matters.

We look forward to continuing to work with you on matters related to drug compounding. If you have questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

Shannon Glueck, PharmD
Acting Branch Chief
Branch 4
Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research

NABP
National Association of Boards of Pharmacy

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Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: December 9, 2021

RE: National Alert Warning Issued in Response to Age-Related COVID-19 Vaccine Mix-Ups Reported to the ISMP VERP

The National Alert Network (NAN) issued an alert regarding a steady stream of reports sent to the Institute for Safe Medicine Practices National Vaccine Errors Reporting Program (ISMP VERP) regarding mix-ups with the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine formulation for children ages five to 11 years old and the Pfizer-BioNTech COVID-19 vaccine formulation for individuals 12 years and older.

Based on reports sent to ISMP VERP, most of the mix-ups occurred in outpatient or ambulatory care settings. Reported cases involved both underdoses (individuals 12 and up receiving the formulation meant for children 5-11 years of age) and overdoses (children aged five to 11 receiving the formulation meant for patients aged 12 and older). Some errors are happening due to vial or syringe mix-ups, while in other errors, health care providers incorrectly thought it was acceptable to give a smaller or diluted dose of the formulation intended for individuals 12 or older to children aged five to 11. Vaccine vials formulated for individuals 12 and up (purple cap) should never be used to prepare doses for the younger age group (orange cap).

Because more than four million children aged five through 11 have been vaccinated to date, the number of errors may be small in comparison. However, ISMP does not want mix-ups between these vaccine formulations to raise concerns of vaccine hesitancy or further undermine public health efforts to vaccinate as many children as possible. These vaccine errors are not expected to cause serious adverse events, and children who received underdoses can be revaccinated.

If providers, including pharmacies, will be administering both adult and pediatric COVID-19 vaccines, develop a plan to reduce the possibility of vaccine mix-ups. Report all vaccine errors internally as well as to the Vaccine Adverse Event Reporting System (VAERS). Please note that reporting to VAERS is mandatory for COVID-19 vaccine errors. ISMP also requests that providers report errors to ISMP VERP.

The full NAN Alert, which provides more information on sources of error as well as prevention recommendations, may be viewed at *https://www.ismp.org/alerts/age-related-covid-19-vaccine-mix-ups.*

NABP encourages you to share this information with licensees within your state.

cc: NABP Executive Committee

NABP
National Association of Boards of Pharmacy

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Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: December 21, 2021

RE: Registration is Open for FDA's 2022 Compounding Quality Center of Excellence Instructor-Led Training Programs

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The Food and Drug Administration (FDA) Compounding Quality Center of Excellence's (CQCoE) training programs provide free training opportunities on manufacturing quality and other policies pertaining to outsourcing facilities, including current good manufacturing practices (CGMPs). The goal is to support outsourcing facilities in their efforts to improve the overall quality of compounded drugs.

FDA's CQCoE is ringing in the new year by **announcing new offerings in 2022 of the popular CQCoE-sponsored virtual, instructor-led courses** designed to support the outsourcing facility industry and improve the overall quality of compounded drugs. In addition to the current course line up, FDA has announced a new process validation course, which is an introductory course that outlines the general principles and approaches for process validation which drive end-product quality by ensuring control at each step of the manufacturing process.

Registration is open for the following multiday, virtual, instructor-led courses:

- Sterile Drug Compounding: January 10-13, 2022; April 18-21, 2022
- Process Validation ***new*****:** January 24-27, 2022; April 11-14, 2022; May 2-5, 2022
- Cleanroom: February 7-10, 2022; May 23-26, 2022
- Environmental Monitoring: March 7-10, 2022
- Investigations and Corrective Preventive Actions (CAPA): March 28-31, 2022

Space is limited and interested persons should request registration as soon as possible, especially for the January courses. Please note that all registration requests are pending until individuals receive an email confirming registration (approximately one week before the course).

FDA also continues to offer free, unlimited attendance and publicly available self-guided online trainings that provide an overview of select CGMPs and policy topics. Please check the CQCoE website for links to existing on-demand courses, and to stay current on additional offerings as they become available. Continuing education (CE) credit is available for all of these courses.

For more information about these trainings, including registration and CE information, please visit *https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence-training-programs.* Please contact the FDA Compounding Quality Center of Excellence at CompoundingQualityCoE@fda.hhs.gov with any questions.

cc: NABP Executive Committee

PHA PROPOSED DISCIPLINARY MATRIX

Violation Type	Statute/Regulation	Precedence List	Recommended Action
Continuing Education			
• Failure to meet continuing education requirements • Failure to comply with mandatory continuing education audit	AS 08.80.165, 12 AAC 02.960(e), 12 AAC 52.300, 12 AAC 52.325, 12 AAC 52.350.	• Civil fine of $250 only (1) • Consent agreement with $200 fine, reprimand, 2 mandatory audits (1) • Consent agreement with $250 fine, reprimand, 2 mandatory audits (1) • Consent agreement with $300 fine, reprimand, 2 mandatory audits (1) • Consent agreement with $1,000 fine, reprimand, 2 mandatory audits (1) • License revocation (7) • License surrender (3)	$100/hour missed ($25/quarter hour missed + consent agreement + 2 mandatory audits *see proposed matrix from paralegal for pharmacists and pharmacy technicians
Falsified Application/failure to disclose – technical			
• *Examples: wrong SSN, forgot to report an aged minor criminal history (e.g.: shoplifting from 20 years ago)*	AS 08.80.261(a)(1), AS08.80.261(a)(14), 12 AAC 52.920(a)(13)	• Non-disciplinary letter of advisement (1) • Civil fine of $500 only (2) • Civil fine of $1,000 only (2) • Civil fine of $2,000 only (2) • Consent agreement with $1,000 fine and reprimand (1) • Consent agreement with $3,000 fine and reprimand (1)	• Non-disciplinary letter of advisement or civil fine of up to $500 • Imposition of civil fine without censure or reprimand (technical violation not related to the delivery of health care); Civil Fine of $1,000 for each violation. Discipline to be commensurate with the severity of the violation.

PHA PROPOSED DISCIPLINARY MATRIX

Falsified Application/failure to disclose – scope of practice			
• *Examples: not qualified for licensure (e.g.: did not really hold a license in another jurisdiction when applied via reciprocity; had license revoked in another jurisdiction and didn't report)* • failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter; (12 AAC 52.920(a)(13))	AS 08.80.261(a)(1), AS08.80.261(a)(14), 12 AAC 52.920(a)(13)	• Non-disciplinary letter of advisement (1) • Civil fine of $500 only (2) • Civil fine of $1,000 only (2) • Civil fine of $2,000 only (2) • Consent agreement with $1,000 fine and reprimand (1) • Consent agreement with $3,000 fine and reprimand (1)	• Civil fine beginning at $500 and up to $3,000 • Imposition of civil fine without censure or reprimand (technical violation not related to the delivery of health care); Civil Fine of $1,000 for each violation. Discipline to be commensurate with the severity of the violation. • License revocation • License denial
Negligence			
• intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision (AS 08.80.261)(a)(5).	12 AAC 52.230 (a)(2), AS 08.80.330(a), AS 08.80.261(a)(5)(6), 12 AAC 52.920(a)(16)	• Non-disciplinary letter of advisement (2) • Consent agreement with $2,750 civil fine (1)	• Civil fine beginning at $500 and up to $3,000 • License revocation • License denial
• intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient; (revocation; 12 AAC 52.920(b)(4))	12 AAC 52.230 (a)(2), AS 08.80.330(a), AS 08.80.261(a)(5)(6), 12 AAC 52.920(a)(16)	• Non-disciplinary letter of advisement (2) • Consent agreement with $2,750 civil fine (1)	• Civil fine beginning at $500 and up to $3,000 • License revocation • License denial
Unlicensed Practice			
• knowingly delegating any aspect of practice of pharmacy to unlicensed person inconsistent with delegation allowed in AS 08 (12 AAC 52.920(a)(16)	AS 08.80.261(a)(14), 12 AAC 52.130 (c), 12 AAC 52.920(a)(3), AS 08.80.261(a)(1), 12 AAC 52.920(a)(13)	• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	Refer to unprofessional conduct.

PHA PROPOSED DISCIPLINARY MATRIX

• Engaging in unlicensed activities defined in "practice of Pharmacy in AS 08.80.480(30), except for tribal pharmacists exempt from licensure in 12 AAC 52.150, provided they submit the required form.		• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	• Non-disciplinary letter of advisement if submitted between 31 days and 90 days • Civil fine of $250 if 91 – 120 days • Civil fine of $500 if 121 – 360 days
• Practicing as an intern before obtaining licensure in the state (12 AAC 52.120)		• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	Relates to delegation of duties on the part of the pharmacist; refer to unprofessional conduct. Consider whether it was inadvertent, a misunderstanding, unknowing misrepresentation vs. intentionally providing fraudulent information. Range of actions may be appropriate.
• Practicing as an intern without personal pharmacist supervision (AS 08.80.480(a)(14)(A))		• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	Consider length of time without personal supervision (e.g.: 1 hour vs. 1 month) • Fine for both (intern = $250, pharmacist = $500)
• Performing manipulative, non-discretionary functions and working in the dispensing area without holding a pharmacy technician license (12 AAC 50.230)		• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	Consider length of time without personal supervision (e.g.: 1 hour vs. 1 month) • Fine for both (tech = $150, pharmacist = $500

• Shipping, mailing, delivering, or advertising pharmacy services without holding an out-of-state pharmacy registration (AS 08.80.158(e)), or without holding a wholesale drug distributor, third-party logistics provider, or outsourcing facility license (AS 08.80.159(a))		• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	• $25,00
• Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license (AS 08.80.157(h)(7))		• Consent agreement with fine excused/letter of advisement (1) • Consent agreement with $5,000 fine (1)	• $25,000
Unprofessional Conduct			
• Knowingly dispenses invalid prescription	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2) • Civil fine of $1,000 (1) • Probation, if repeated
• Dispenses unsafe quantities/dosages/supply-days	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2) • Civil fine of $1,000 (1) • Probation, if repeated
• Acquiring, possessing, or attempting to possess Rx in criminal or nefarious manner		• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) Civil fine of $500 (2)	• License revocation • License suspension for up to two years AND probation for at least two years for: willfully/repeatedly violating AS 08 or 12 AAC 52 OR for professional incompetence
• Distributing Rx to practitioner/pharmacy outside of professional practice	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500

PHA PROPOSED DISCIPLINARY MATRIX

		• Civil fine of $500 (2)	• Civil fine of $1,000
• Refusing to keep, maintain, or furnish records	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000
• Refusing Inspection	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000
• Making false claims for reimbursements	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Reprimand, if minimal/infrequent • License suspension • License Probation • License Revocation
• Operating an unsafe pharmacy	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Consider USP 797/795 • Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
• Refilling Rx > 1 year than date of issue	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Probation, if repeated
• Violating a board order or agreement	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation

PHA PROPOSED DISCIPLINARY MATRIX

• Failing to provide information or providing false information on a form/application	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	Refer to fraud/misrepresentation or failure to report/submit
• Failing to establish/maintain effective controls against diversion/loss	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 (non CS) • Civil fine of $500 (non CS) • Civil fine of $1,000 (CS)
• Failing to use reasonable knowledge, skills, judgment	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
• Knowingly delegating any aspect of practice of pharmacy to unlicensed person inconsistent with delegation allowed in AS 08	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
• Failing to exercise adequate supervision	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
• Violating confidentiality of records	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000

PHA PROPOSED DISCIPLINARY MATRIX

			• License Suspension • License Probation • License Revocation
• Discrimination	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• License Suspension • License Probation • License Revocation
• Offering, giving, soliciting, receiving compensation for patient referrals	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
• Violating PDMP requirements	12 AAC 52.920	• Non-disciplinary letter of advisement (1) • Civil fine of $250 (1) • Civil fine of $500 (2)	• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation • Depending on violation, may be misdemeanor/felony
Fraud or Misrepresentation			
• Secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation	AS 08.80.261, 12 AAC 52.920	• Non-disciplinary letter of advisement (2) • License surrender (1) • Civil fine of $3,000 (1)	• Reprimand; Civil Fine of at least $10,000; License suspension for a minimum of 30 days. Discipline to be commensurate with the severity of the violation. • License revocation • License suspension for up to two years AND probation for at least two years for willfully/repeatedly violating AS 08 or 12 AAC 52 OR for professional incompetence

PHA PROPOSED DISCIPLINARY MATRIX

• Engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;	AS 08.80.261, 12 AAC 52.920	• Non-disciplinary letter of advisement (2) • License surrender (1) • Civil fine of $3,000 (1)	• Reprimand; Civil Fine of at least $10,000; License suspension for a minimum of 30 days. Discipline to be commensurate with the severity of the violation. • License revocation • License suspension for up to two years AND probation for at least two years for willfully/repeatedly violating AS 08 or 12 AAC 52 OR for professional incompetence
Prohibited Advertising/Use of Symbols			
• Using the following terms without the business having a regular/continuously employing a licensed pharmacist: ○ Pharmacist ○ Assistant pharmacist ○ Druggist ○ Pharmacy ○ Drug store ○ Drug sundries ○ Drug	AS 08.80.430		• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
• Using the symbol, “Rx” in any form unless the business has a licensed pharmacist	AS 08.80.430		• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • License Suspension • License Probation • License Revocation
Violation of Change Requirements			
• Pharmacist-in-charge change form not submitted within 10 days	12 AAC 52.200		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine

			• ≥ 1 year = $500 fine
• PIC failing to submit a new initial application following a change in physical location or name or failing to submit a new application resulting from a change in ownership	12 AAC 52.030, 12 AAC 52.040		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine • ≥ 1 year = $500 fine
• Wholesale drug distributor facility manager change form, resume, fingerprints, and fee not submitted within 30 days	12 AAC 52.610		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine • ≥ 1 year = $500 fine
• Outsourcing facility or third-party logistics provider does not submit a new initial application following change of facility manager, ownership, or location within 30 days	12 AAC 52.696, 12 AAC 52.697		• If 1 – 3 days = grace period • 4 – 7 days = letter of advisement • 8 – 14 days = $100 fine • 15 – 30 days = $200 fine • 30 days ≤ than a year = $300 fine • ≥ 1 year = $500 fine
Failure to Report/Submit			
• Pharmacist-in-charge does not submit an inspection report for a pharmacy that has changed its physical location within 14 days	12 AAC 52.030		• 1 – 5 days late = letter of advisement • 6 days – 1 month late = $250 fine • > 1 month – 6 months late = $500 fine • > 6 months – 1 year = $1,000 fine • ≥ 1 year = $1,250 fine
• Failure to report information to the board relating to an applicant or licensee who was incapable of engaging in the practice of pharmacy	AS 08.80.261(a)(12)		• Non-disciplinary letter of advisement • Civil fine of $250 • Civil fine of $500 • Civil fine of $1,000 • Suspension • Revocation
• Failure of an intern to file a report of experience within 30 days	12 AAC 52.220		• Non-disciplinary letter of advisement

following completion or termination of an internship			
• Failure to submit a copy of DEA form 106 following a theft or loss of a controlled substances	12 AAC 52.540		• There is no timeframe currently required in 12 AAC 52; consider requiring the form to be submitted within 1 day consistent with DEA requirements
• Failure to report a disciplinary decision or felony conviction affecting the applicant's or licensee's ability to practice safely and competently within 30 days	12 AAC 52.991(a)		• 1 – 5 days late = letter of advisement • 6 days – 1 month late = $250 fine • > 1 month – 6 months late = $500 fine • > 6 months – 1 year = $1,000 fine • ≥ 1 year = $1,250 fine • Consider severity
• Failure of a pharmacy or facility to report any disciplinary action to the board	12 AAC 52.991(b)		• There is no timeframe currently required in 12 AAC 52; consider requiring notices to be submitted within 30 days consistent with 12 AAC 52.991(a) • 1 – 5 days late = letter of advisement • 6 days – 1 month late = $250 fine • > 1 month – 6 months late = $500 fine • > 6 months – 1 year = $1,000 fine • ≥ 1 year = $1,250 fine • Consider severity

Action/Authority	Criteria
Limitation12 AAC 52.920	• Licensees who practice or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy (12 AAC 52.920(d))
Probation 12 AAC 52.930, 12 AAC 52.940, 12 AAC 52.950, 12 AAC 52.960	• Licensees completing a two-year suspension as a result of willfully/repeatedly violating statutes and/or regulations or for practicing incompetently and placing the public at risk (12 AAC 52.920(c) • Terms of probation include requirements for licensees to (12 AAC 52.930): ○ Obey all laws relating to practice of pharmacy ○ Fully comply with probation program established by board ○ Notify board in writing of dates of departure/return if the licensee leaves state ○ Report into the board during meetings ○ Submit written reports and verifications to the board ○ Submit documentation from employer acknowledging employee's probation

	○ Be employed as a pharmacist only under supervision and does not act as a supervisor • Terms of probation involving alcohol or controlled substances (12 AAC 52.940): ○ Physical and mental health exams ○ Participation in rehabilitative program ○ Abstain from personal use of substance ○ Submit to testing and sampling ○ Restricted access to controlled substances while employed • Terms of probation for professional incompetence (12 AAC 52.950): ○ Successful completion of course as determined by the board before the end of probationary period or ○ 15 additional hours of appropriate continuing education • Terms of probation for mental or physical disabilities (12 AAC 52.960; review similarities in 12 AAC 52.930): ○ Physical and mental health examinations ○ Completion of treatment program that includes progress reports from care provider
Suspension AS 08.80.157(h), AS 08.80.158(d)	• Pharmacies and facilities: ○ Violating state or federal law ○ Felony conviction of owner of facility ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution ○ Suspension or revocation of federal, state, or local jurisdiction ○ Obtaining renumeration by fraud or deceit ○ Dealing with drugs or devices known to have been stolen ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license ○ A pharmacy failing to comply with applicable laws (AS 08.80.158(d)) ○ • Individuals: ○ Felony conviction of pharmacy employee ○ Applicants/licensees for emergency permits/courtesy license
Revocation 12 AAC 52.920, AS 08.80.157(h), AS 08.80.158(d)	• Licensees who practice or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy (12 AAC 52.920(d)) • Pharmacies and facilities: ○ Violating state or federal law ○ Felony conviction of owner of facility ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution ○ Suspension or revocation of federal, state, or local jurisdiction

	○ Obtaining renumeration by fraud or deceit ○ Dealing with drugs or devices known to have been stolen ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license ○ A pharmacy failing to comply with applicable laws (AS 08.80.158(d)) • Individuals: • Felony conviction of pharmacy employee • Applicants/licensees for emergency permits/courtesy license
Deny AS 08.80.157(h), AS 08.80.158(d), AS 08.80.261	• Anything listed in AS 08.80.261 • Pharmacies and facilities: ○ Violating state or federal law ○ Felony conviction of owner of facility ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution ○ Suspension or revocation of federal, state, or local jurisdiction ○ Obtaining renumeration by fraud or deceit ○ Dealing with drugs or devices known to have been stolen ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license ○ A pharmacy failing to comply with applicable laws (AS 08.80.158(d)) • Individuals: • Felony conviction of pharmacy employee • Applicants/licensees for emergency permits/courtesy license
Refuse to renew AS 08.80.157(h)	• Pharmacies and facilities: ○ Violating state or federal law ○ Felony conviction of owner of facility ○ Providing false or fraudulent information on an application related to drug/device manufacturing or distribution ○ Suspension or revocation of federal, state, or local jurisdiction ○ Obtaining renumeration by fraud or deceit ○ Dealing with drugs or devices known to have been stolen ○ Distributing drugs or devices directly to patients without holding a wholesaler or pharmacy license • Individuals: • Felony conviction of pharmacy employee • Applicants/licensees for emergency permits/courtesy license

Board of Pharmacy PDMP Policies & Procedures

Summary: These policies and procedures are to be followed when processing account registrations and adding pharmacies to the compliance monitoring function. Additional details, requirements, and procedures are located in the PHA desk manual and PDMP resources folder.	Date drafted: 08/06/2019 Date revised: 01/24/2022

I. Registration

A. Initial assessment & data entry

1. Occupational licensing examine (OLE) screens pharmacist application for licensure in accordance with OL-578 or OL-719. Fill out the PDMP checklist, OL-740 concurrently.
2. If the pharmacist applicant indicates their intent to dispense federally scheduled II – IV controlled substances in Alaska, enter the 'Dispensing', 'Controlled Substances' designation into their Portal record.
3. Add the pharmacist's name to the delayed registration tracker.
4. If a pharmacist is in regular communication with you regarding imminent completion of required exams for licensure, use this as an opportunity to proactively remind them to register.

B. Tickler & timeframe notification

1. The registration requirement for pharmacists starts only when their license is issued.
2. Registration must be complete within 30 days of licensure/dispensing. Calculate 30 days from the date of license issuance and create a 'PDMP Registration' tickler with this date as the due date. Tip: use the date duration calculator.
3. On the day the license is issued, notify the executive administrator (EA). The EA will send via certified mail a formal notice to the pharmacist of their requirement to register. As a courtesy, it is recommended the OLE also send a reminder to the pharmacist via email.

C. Account assessment & approval

1. On a weekly basis, navigate to 'Search' → 'Tickler' in Portal and search by the 'PDMP Registration' tickler. Go down the list of names and login to AWARxE and navigate to the 'User Administration' → 'Registration' tab to see if the pharmacist submitted their registration request. It's possible the pharmacist already has an account (as an intern or federal role, so double check the 'Users' tab. There may also be an ebb and flow with issuing pharmacist licenses; check for their registration in AWARxE as applicants notify you they have passed their required exams and whose licenses are ready to be issued.
2. If their registration access request is present in AWARxE, assess their account details to make sure they match up in Portal, e.g.: spelling of name, DOB, SSN, license #, etc. Also check that their specialty is appropriate. Make corrections as appropriate.
3. Once all account details are accurate, approve the request and mark the tickler as complete AND create a 'Report' event detail (this is temporary only).
4. Return to the delayed tracker and mark the pharmacist as complete.

D. Delayed/no registration & INV referral

1. If the pharmacist does not register within 30 days, refer the matter to the EA per P&P28.
2. Update the delayed registration tracker with the date the matter is referred to the EA.
3. The EA will assess the referral, and if deemed necessary, will transmit it to the Chief Investigator and enter the matter onto the 'Yes' answer spreadsheet.

II. Reporting

A. Initial assessment & data entry

1. OLE screens pharmacy application for licensure in accordance with OL-751. There is no corresponding PDMP checklist for this aspect.
2. If the pharmacy indicates they will be dispensing/distributing federally scheduled II – IV controlled substances, enter a DEA Registration designation into their Portal record and check the DEA Registered box.
3. Add the pharmacy to the controlled substance distribution list.

B. Adding pharmacy to compliance

1. Login to AWARxE and navigate to 'Compliance'. Within the 'Manage Pharmacies' page, search the pharmacy's DEA to see if they've already been added, e.g.: under a previous license.
2. If the pharmacy has not been added, navigate to 'Add Pharmacies'. Copy the DEA # from the controlled substance distribution list and hit the down-arrow button to auto fill.
3. Copy and paste the pharmacy's additional contact information from the distribution list spreadsheet.

C. Delayed/no reporting (this work function will be completed by the PDMP Manager, PDMP project assistant, and/or PDMP OLE).

Board of Pharmacy - Prescription Drug Monitoring Program
Approved Disciplinary Matrix ~~as of February 18, 2021~~

Complaint	Proposed Sanctions
Registration (AS 17.30.200(e)(n), 12 AAC 52.855): • No registration • Delayed registration – not registered within 30 days • Delayed dispensing status, including dispensation exemption form – not submitted within 10 days	(Notice sent on July 7, 2020 via board letter to all pharmacists with Alaska addresses). $250 civil fine beginning on October 1, 2020 (or after 30 days of initial licensure or after beginning to dispense schedule II, III, or IV federally controlled substances) and an additional $25 per day until registration is completed. $250.00 civil fine for each day after the 10th day of not submitting the dispensing notice of change to the board.
Delinquent Reporting (AS 17.30.200(b)(e), 12 AAC 52.865): • Daily reporting (12 AAC 52.865)(b)) • Delayed dispensing/distributing status – not submitted within 10 days	(Warning issued September 16, 2020 via board letter to all licensees). As of January 1, 2021, quarterly compliance audits will track* delinquent submissions of data to the PDMP. • First reprimand: $5,000 civil fine for continued submission delinquencies • ~~Continued submission delinquencies may result in license suspension. A "continued submission delinquency" means a pharmacy that has not reported or responded to notices by the Board.~~ Reporting delinquency is defined as a pharmacy that missed at least one reporting day within a 30-day period. ○ Appear on monthly list for first time = warning letter ○ Appear on monthly list again = $5,000 civil fine • Dispensing status not submitted timely: $250 civil fine for each day after the 10th date of not submitting the notice of change to the board
Unauthorized Access (AS 17.30.200(d)(4))	TBD

*During its May 2021 meeting, the board agreed to begin monitoring compliance daily with referrals to the Investigative Unit to include all pharmacies delinquent on at least one day. The new monthly analysis will begin on July 1st and the first round of referrals will be transmitted on August 1st.

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Statutes and Regulations
Pharmacy

May 2021

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

NOTE: The official version of the statutes in this document is printed in the Alaska Statutes, copyrighted by the State of Alaska. The official version of the regulations in this document is published in the Alaska Administrative Code, copyrighted by the State of Alaska. If any discrepancies are found between this document and the official versions, the official versions will apply.

Rev. 5/14/2021

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CHAPTER 80. PHARMACISTS AND PHARMACIES

Article

ARTICLE 1. THE BOARD OF PHARMACY

Section

Sec. 08.80.003. PRACTICE OF PHARMACY AS A PROFESSION. The practice of pharmacy is declared to be a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest that only qualified persons be permitted to engage in the practice of pharmacy, and to ensure the quality of drugs and related devices distributed in the state.

Sec. 08.80.005. STATEMENT OF PURPOSE. It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Sec. 08.80.010. CREATION AND MEMBERSHIP OF BOARD; OFFICERS. (a) There is created the Board of Pharmacy, composed of seven members, five of whom shall be pharmacists licensed in the state who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. Two shall be persons with no direct financial interest in the health care industry. Whenever possible, the board shall include at least one member from each judicial district.

(b) An officer elected by the board serves a term of one year and may not serve more than four consecutive full terms in a specific office.

Sec. 08.80.020. Term of office. *[Repealed, Sec. 20 ch 80 SLA 1996.]*

Sec. 08.80.030. POWERS AND DUTIES OF THE BOARD. (a) The board is responsible for the control and regulation of the practice of pharmacy.

(b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent administration by a pharmacist of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o);

(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business;

(16) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

(c) The board shall post and maintain a link to the United States Food and Drug Administration's list of all currently approved interchangeable biological products on the board's Internet website.

(d) The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of secs. 201 - 208, P.L. 113-54 (Drug Supply Chain Security Act).

Sec. 08.80.040. Duties of the board. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.045. NONPRESCRIPTION DRUGS. (a) Except as provided in (b) of this section the board may not regulate the sale of patent or nonprescription drugs that are prepackaged for use by the consumer, are in their original, unbroken packaging, and are labeled in accordance with requirements of the federal government.

(b) The board may regulate the sale and distribution of patent or nonprescription drugs under AS 44.62.250 when the regulation is required by an emergency to protect the public health and safety.

Sec. 08.80.050. APPLICABILITY OF ADMINISTRATIVE PROCEDURE ACT. The board shall comply with AS 44.62 (Administrative Procedure Act).

Sec. 08.80.060. MEETINGS OF THE BOARD. The board shall meet at least three times each year at the call of the president for the transaction of business properly before it. The president shall also call the board into session when requested in writing by at least two members. Meetings may be held telephonically.

Sec. 08.80.070. QUORUM. Four members constitute a quorum for the transaction of business. However, when the board meets for the purpose of examining applications for licensure, three members of the board constitute a quorum.

Sec. 08.80.080. EXPENSES OF MEMBERS. Members of the board are entitled to reimbursement for actual travel expenses incidental to the discharge of their duties and, while in the performance of their duties, are entitled to the per diem expenses allowed by law.

Sec. 08.80.090. Disposition of fees. *[Repealed, Sec. 54 ch 37 SLA 1985.]*

Sec. 08.80.100. Board secretary as certifying officer. *[Repealed, Sec. 3 ch 59 SLA 1966.]*

Sec. 08.80.105. REMOVAL OF BOARD MEMBERS. A member of the board may be removed from office by the governor for cause.

ARTICLE 2. LICENSING AND REGISTRATION

Section

159. Licensing and inspection of facilities outside of state
160. Fees
165. Continuing education requirements
168. Administration of vaccines and related emergency medications
261. Disciplinary sanctions
270. Executive administrator of the board

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall

(1) be fluent in the reading, writing, and speaking of the English language;

(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(3) be a graduate of a college in a degree program approved by the board;

(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;

(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.115. Registration of pregraduate and postgraduate intern pharmacist. *[Repealed, Sec. 40 ch 177 SLA 1978.]*

Sec. 08.80.116. INTERNSHIP AND OTHER TRAINING PROGRAMS. (a) An applicant for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under terms and conditions the board shall determine.

(b) The board shall establish licensure requirements for interns and standards for internship or other training programs that are necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of preceptors used in practical experience programs.

Sec. 08.80.117. Malpractice insurance. *[Repealed, Sec. 7 ch 94 SLA 1980.]*

Sec. 08.80.120. GRADING AND CONTENT OF EXAMINATION. The examination or examinations shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with an organization or consultant in the preparation and grading of an examination, but shall retain sole discretion and responsibility for determining which applicants have successfully passed the examinations.

Sec. 08.80.130. Reexamination. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.140. License by credentials. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

(1) submits a written application to the board on a form required by the board;

(2) is at least 18 years of age;

(3) is of good moral character;

(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;

(5) has engaged in the practice of pharmacy for at least one year or has met the internship requirements of this state within the one-year period immediately before applying for a license under this section;

(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;

(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and

(8) pays all required fees.

Sec. 08.80.147. RENEWAL OF LICENSURE. If a pharmacist fails to apply for renewal of a license within five years from the expiration of the license, the person must pass an examination for license renewal, except that a person who has continually practiced pharmacy in another state under a license issued by the authority of that state may renew an expired license in this state upon fulfillment of the requirements that may be established by the board.

Sec. 08.80.150. TEMPORARY LICENSE. The board shall adopt regulations regarding the issuance of a temporary license to practice pharmacy.

Sec. 08.80.155. EMERGENCY PERMIT. The board shall adopt regulations regarding the issuance of an emergency permit to practice pharmacy.

Sec. 08.80.157. LICENSING OF FACILITIES. (a) A facility engaged in the practice of pharmacy or in the manufacture, production, or wholesale distribution of drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be licensed by the board, and shall renew the license at intervals determined by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

(b) The board may by regulation determine the licensure classifications of facilities and establish minimum standards for the facilities.

(c) The board shall establish by regulation the criteria that a facility must meet to qualify for licensure in each classification. The board may issue licenses with varying restrictions to facilities when the board considers it necessary to protect the public interest.

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(e) Licenses issued by the board are not transferable or assignable.

(f) The board shall specify by regulation the minimum standards for responsibility of a facility or pharmacy that has employees or personnel engaged in the practice of pharmacy or engaged in the manufacture, wholesale distribution, production, or use of drugs or devices in the conduct of its business.

(g) A licensed facility shall report to the board

(1) permanent closing;

(2) change of ownership, management, location, or pharmacist-in-charge of a pharmacy;

(3) theft or loss of drugs or devices as defined by regulations of the board;

(4) conviction of an employee of violation of a state or federal drug law;

(5) disasters, accidents, theft, destruction, or loss relating to records required to be maintained by state or federal law;

(6) occurrences of significant adverse drug reactions as defined by regulations of the board;

(7) other matters and occurrences the board may require by regulation.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy;

(8) violation of this chapter or a regulation adopted under this chapter.

(i) The board's regulations under (b) - (d) and (f) of this section may not establish more stringent licensing requirements for the facilities governed by AS 08.80.390 than are set out in AS 08.80.390.

(j) This section does not apply to the offices of physicians, osteopaths, podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians, dispensing opticians, or optometrists.

(k) This section applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

Sec. 08.80.158. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE. (a) A pharmacy located outside of the state that regularly ships, mails, or delivers prescription drugs to consumers in the state shall register with the board.

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; and

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy.

(c) A pharmacy subject to this section shall, during its regular hours of operations, provide a toll-free telephone service to facilitate communication between persons in the state and a pharmacist at the pharmacy who has access to records concerning the dispensing of prescription drugs to persons in the state. The toll-free number and the hours that the service is available shall be disclosed on a label affixed to each container of drugs dispensed to persons in the state. The telephone service shall be available at least 40 hours a week and at least six days a week.

(d) The board may, after a hearing, deny, revoke, or suspend the registration of a pharmacy located outside of the state and subject to this section if the pharmacy fails to comply with the requirements of this section, AS 17.20.080 - AS 17.20.135, or AS 17.30.020 - 17.30.080, or if the license, permit, or registration of the pharmacy is denied, revoked, or suspended by the licensing or regulatory agency of the jurisdiction in which the pharmacy is located.

(e) A pharmacy located outside of the state that is subject to this section but is not registered with the board under this section may not ship, mail, or deliver prescription drugs into the state and may not advertise its services in the state.

(f) A pharmacy subject to this section shall appoint a registered agent in the state who is empowered to accept, on behalf of the pharmacy, process, notice, and demand required or permitted by law to be served upon the pharmacy. If the pharmacy fails to appoint an agent under this subsection, if the registered agent cannot with reasonable diligence be found at the registered office, or if the registration of the pharmacy is suspended or revoked, the commissioner of commerce and economic development is an agent upon whom process, notice, or demand may be served. Service is made upon the commissioner in the same manner as provided for corporations under AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the address shall be the last registered address of the pharmacy as shown by the records of the board.

(g) The board shall by regulation define “regularly” for this section.

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. (a) Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

(1) obtain a license under AS 08.80.157;

(2) appoint an agent on whom process can be served in the state; and

(3) authorize inspection of the facility by a designee of the board under (c) of this section.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

(1) register as an outsourcing facility with the United States Food and Drug Administration; and

(2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may

(1) require an inspection of the applicant's facility located outside the state; and

(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;

(2) reexamination;

(3) investigation for licensing by license transfer;

(4) pharmacist license;

(5) temporary license;

(6) pharmacy technician license;

(7) pharmacy intern license;

(8) emergency permit;

(9) license amendment or replacement;

(10) registration or licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.165. CONTINUING EDUCATION REQUIREMENTS. The board shall establish requirements for continuing education in pharmacy that must be satisfied before a license issued under this chapter may be renewed.

Sec. 08.80.168. ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS.

(a) A pharmacist may independently administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(b) A pharmacist may independently dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(c) In this section,

(1) "opioid overdose drug" has the meaning given in AS 17.20.085;

(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

Sec. 08.80.170-08.80.210. Fees. *[Repealed, Sec. 7 ch 24 SLA 1968.]*

Sec. 08.220. Prescription department required for issuance of license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.230. Sanitary conditions required for issuance of license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.240. Form and display of registration certificate and license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.250-08.80.260. Renewal of lapsed registration; ground for refusing or revoking a license. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.261. DISCIPLINARY SANCTIONS. (a) The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable,

(1) secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or a drug that impairs the applicant's or licensee's ability to practice safely;

(D) physical or mental disability; or

(E) other factors determined by the board;

(8) engaged in conduct involving moral turpitude or gross immorality;

(9) made a controlled substance available to a person except upon prescription issued by a person licensed to prescribe controlled substances;

(10) was convicted of selling federal legend drugs without the prescription of a person licensed to prescribe federal legend drugs;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(12) failed to report relevant information to the board about a pharmacist or pharmacy intern that the applicant or licensee knew or suspected was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public;

(13) aided another person to engage in the practice of pharmacy or to use the title of "pharmacist" or "pharmacy intern" without a license; or

(14) engaged in unprofessional conduct, as defined in regulations of the board.

(b) The board may place under seal all drugs that are owned by or in the possession, custody, or control of a licensee at the time a license is suspended or revoked or at the time the board refuses to renew a license. Except for perishable items, the drugs may not be disposed of until the licensee has exhausted administrative and judicial remedies relating to the licensing action. Perishable items may be sold upon order of the court with the proceeds to be deposited with the court. The board shall notify the Department of Health and Social Services about drugs placed under seal under this subsection.

Sec. 08.80.265. Limits or conditions on license; discipline. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.266. Disciplinary sanctions. *[Repealed, Sec. 49 ch 94 SLA 1987.]*

Sec. 08.80.270. EXECUTIVE ADMINISTRATOR OF THE BOARD. (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS

39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

ARTICLE 3. DUTIES OF LICENSED PHARMACISTS

Section

Sec. 08.80.270-08.80.290. Report of employees and goods sold; affixing labels. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.294. INFORMATION ABOUT EQUIVALENT GENERIC DRUGS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order that is

(1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed;

(2) a biological product, shall include the dispensed product's

(A) proprietary name, if available; or

(B) proper name.

(b) The generic drug name or proprietary or proper biological product name required under (a) of this section shall be placed directly on the container's label near the brand name.

(c) In this section,

(1) "proper name" means a name that reflects scientific characteristics of the product such as chemical structure and pharmacological properties;

(2) "proprietary name" means a name that is trademarked and registered for private use.

Sec. 08.80.295. SUBSTITUTION OF EQUIVALENT DRUG PRODUCTS OR INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product or interchangeable biological product.

(b) A pharmacist who substitutes an equivalent drug product or interchangeable biological product in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.

(c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows:

(1) by making an entry that is electronically accessible to the prescribing practitioner through

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record; or

(2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner.

(d) The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription.

(e) Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner.

(f) A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.

(g) In this section, "designee" means an agent or employee of the dispensing pharmacist whom the dispensing pharmacist has authorized to communicate the information required under (c) of this section.

Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES. (a) A pharmacist shall disclose the price of filling any prescription when requested by the consumer.

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;

(B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);

(C) a plan offered under AS 39.30.090 or 39.30.091;

(D) a federal governmental plan as defined under AS 21.54.500;

(E) the Medicaid or Medicare program; or

(F) a self-insured employer benefit plan;

(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

Sec. 08.80.300. Record of prescriptions. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.310. Record of sales. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.315. CONFIDENTIALITY OF RECORDS. Information maintained by a pharmacist in the patient's records or that is communicated to the patient as part of patient counseling is confidential and may be released only to

(1) the patient or as the patient directs;

(2) a practitioner or pharmacist when, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well-being; and

(3) other persons or governmental agencies authorized by law to receive confidential information.

Sec. 08.80.320. Pharmacist required. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.330. LICENSED PHARMACIST APPOINTED AS "PHARMACIST-IN-CHARGE". (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an applicable law or regulation requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist-in-charge, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise. The pharmacist-in-charge shall ensure compliance with all laws and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment.

(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist-in-charge whose name appears on the face of the license.

Sec. 08.80.335. PRESCRIPTION FOR AN OPIOID; VOLUNTARY REQUEST FOR LESSER QUANTITY. (a) A pharmacist filling a prescription for an opioid that is a schedule II or III controlled substance under federal law may, at the request of the individual for whom the prescription is written, dispense the prescribed opioid in a lesser quantity than prescribed.

(b) Nothing in this section shall be construed to prevent substitution of an equivalent drug under AS 08.80.295.

Sec. 08.80.340-08.80.370. Requirements for handling drugs; general prohibitions. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

ARTICLE 4. UNLAWFUL ACTS

Section

Sec. 08.80.380 Issuance of shopkeepers permits. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.390. PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS. (a) A hospital, clinic, nursing home, infirmary, or related facility that provides dispensing of drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.

(b) The board shall issue a license to a hospital drug room, nursing home drug room, or related facility that dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.

Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED. A person may not assume or use the title "pharmacist," or any variation of the title, or hold out to be a pharmacist, without being licensed.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Sec. 08.80.430. USE OF PHARMACY SYMBOLS PROHIBITED. A person may not display in a place of business the characteristic pharmacy symbol of "Rx" in any form unless the business has a pharmacist licensed under this chapter.

Sec. 08.80.440. Denial of examination or license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.450. DISCIPLINARY ACTION. The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a licensee, or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority and filed with the secretary of the board. The accused shall receive an authenticated copy of the order.

Sec. 08.80.460. PENALTIES. (a) Except for a violation of AS 08.80.297, a person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) A person who violates the provisions of AS 08.80.295 or 08.80.297 may be punished by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

ARTICLE 5. GENERAL PROVISIONS

Section

Sec. 08.80.470. CONSTRUCTION. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.20 (the Alaska Food, Drug and Cosmetic Act), or AS 17.30.

Sec. 08.80.475. FEDERAL FACILITIES NOT AFFECTED. This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in a federally operated hospital or institution.

Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires,

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound;

(3) "board" means the Board of Pharmacy;

(4) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(5) "controlled substance" has the meaning given in AS 11.71.900;

(6) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(7) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(8) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(9) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(10) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(11) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug, drug-food, and drug-disease interactions;

(G) adverse drug reactions; and

(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(13) "interchangeable biological product" means a biological product that the United States Food and Drug Administration has determined

(A) meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(14) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(15) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor or a nonprescription drug or commercially packed legend drug or device;

(16) "legend drug" means a prescription drug;

(17) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices; "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(18) “nonprescription drug” means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(19) “outpatient dispensing” means dispensing drugs for administration outside of the hospital pharmacy’s control;

(20) “outsourcing facility” means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location;

(21) “owner” means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(22) “patient counseling” means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(23) “person” has the meaning given in AS 01.10.060 and also includes a governmental agency;

(24) “pharmaceutical care” is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(25) “pharmacist” means an individual currently licensed by this state to engage in the practice of pharmacy;

(26) “pharmacist-in-charge” means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy’s personnel;

(27) “pharmacy” means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS 08.80.157(b);

(28) “pharmacy located outside of the state” means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(29) “pharmacy technician” means a supportive staff member who works under the immediate supervision of a pharmacist;

(30) “practice of pharmacy” means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the administration of vaccines and related emergency medication; the independent dispensing of opioid overdose drugs; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

(31) “practitioner” means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

(32) “preceptor” means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;

(33) “prescription drug” means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) “Caution: Federal law prohibits dispensing without prescription”; (B) “Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian”; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;

(34) “prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient;

(35) “prospective drug use review” means a review of the patient’s drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;

(36) “significant adverse drug reaction” means a drug-related incident that may result in serious harm, injury, or death to the patient;

(37) “substitute” means to dispense, without the prescriber's expressed authorization,

(A) an equivalent drug product in place of the prescribed drug; or

(B) an interchangeable biological product in place of the prescribed biological product;

(38) “third-party logistics provider” means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product;

(39) “wholesale” means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

(40) “wholesale drug distributor” means anyone engaged in wholesale distribution of drugs, including manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Sec. 08.80.490. SHORT TITLE. This chapter may be known as the Pharmacy Act.

CHAPTER 52.
BOARD OF PHARMACY.

Article

ARTICLE 1.
LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS.

Section

12 AAC 52.010. CLASSIFICATIONS OF LICENSURE. (a) The board will issue the following categories of licenses or permits to a qualified individual:

(1) pharmacist license;
(2) temporary pharmacist license;
(3) emergency permit to practice pharmacy;
(4) pharmacist intern license;
(5) pharmacy technician license.

(b) The board will issue the following categories of licenses or registrations to a qualified facility:

(1) pharmacy license;
(2) repealed 2/26/2000;
(3) wholesale drug distributor license;
(4) drug room license;
(5) registration of a pharmacy located outside of the state;
(6) remote pharmacy license;

(7) third-party logistics provider license;
(8) outsourcing facility license;
(9) license of a wholesale drug distributor located outside of the state.

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158
AS 08.80.030 AS 08.80.155 AS 08.80.159
AS 08.80.116 AS 08.80.157 AS 08.80.390

12 AAC 52.020. FACILITY LICENSE. (a) An applicant for a facility license shall submit
(1) the fees required in 12 AAC 02.310;
(2) a completed application on a form provided by the department;
(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and
(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.
(b) Repealed 1/17/2007.
(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.
(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (a) The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall
(1) submit a new, completed application for a pharmacy license; and
(2) pay the duplicate license fee required in 12 AAC 02.105;
(3) repealed 1/17/2007.
(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (a) Repealed 1/17/2007.
(b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.050. CLOSED PHARMACIES. (a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall
(1) submit written notice to the board of the cessation of pharmacy operations on a form provided by the department; the form must be submitted within 10 days after the cessation of operations and include
(A) the date the pharmacy ceased operations;
(B) a statement signed by the pharmacist-in-charge attesting that an inventory of all controlled substances on hand has been conducted; and
(C) a statement signed by the pharmacist-in-charge attesting to the manner of disposition for all prescription drugs possessed by the pharmacy;
(2) arrange for the transfer of prescription drug orders or computer prescription records to another pharmacy to facilitate continuous patient care; and
(3) provide for the maintenance and availability of prescription drug orders or hard copies of computer prescription records in accordance with 12 AAC 52.450(a) that are not transferred to another pharmacy;
(4) repealed 1/17/2007.
(b) In the absence of a pharmacist-in-charge, the owner of the pharmacy shall meet all requirements of this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.060. FIRE OR OTHER DISASTER. (a) If a pharmacy has a fire or other disaster, the pharmacist-in-charge of the pharmacy shall

(1) within 10 days, report to the board the date of a fire or any disaster that may affect the strength, purity, or labeling of drugs, devices, or other materials used in the practice of the pharmacy;

(2) provide the board with a copy of a completed DEA Form 106, "Report of Theft or Loss of Controlled Substances," reporting the loss or destruction of controlled substances or DEA order forms; if the extent of the loss of controlled substances cannot be determined, the pharmacist-in-charge shall submit to the board a complete inventory of all remaining controlled substances and a statement, signed by the pharmacist-in-charge, attesting to the accuracy of the inventory; and

(3) notify the board in writing within 10 days after any change in the pharmacy's address, including a move to a temporary location or a return to the pharmacy's permanent location.

(b) If a pharmacy maintains a temporary location for more than 90 days, the pharmacist-in-charge of the pharmacy shall apply for a new and separate facility license as required in 12 AAC 52.030.

(c) A pharmacy may not dispense any drug that has been exposed to excessive heat, smoke, or other conditions that may have caused deterioration.

(d) In this section, "other disaster" includes any disaster situation that causes a pharmacy the need to move to a temporary location or results in damage to the drug or device inventory.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (a) An applicant who meets the requirements of AS 08.80.110, 08.80.116, and the requirements set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by examination.

(b) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080, sent directly to the department from the agency where the hours of internship or experience were completed;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

Editor's note: Information about accredited colleges of pharmacy may be obtained from the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109. Information about Foreign Pharmacy Graduate Examination Committee certification and colleges recognized by that committee may be obtained from the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, IL 60056.

12 AAC 52.075. GOOD MORAL CHARACTER. As used in AS 08.80, "good moral character" includes not having been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE. (a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

(b) The board will accept as internship experience only internship hours completed under the direct supervision of a pharmacist licensed under AS 08.80 or the pharmacy licensing laws of another state.

(c) Repealed 4/16/2016.

(d) An internship program in a nontraditional site, such as an industry sponsored program, must be approved by the board before the board will give any internship credit for the program.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110 AS 08.80.116

12 AAC 52.090. EXAMINATION REQUIREMENTS AND REGISTRATION. (a) In addition to the requirements in AS 08.80.110, an applicant for a pharmacist license shall pass the

(1) North American Pharmacy licensing examination (NAPLEX) administered by the National Association of Boards of Pharmacy with a NAPLEX scaled score of 75 or above; and

(2) Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(b) An applicant for a temporary pharmacist license shall pass the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(c) An applicant for a pharmacist license that has passed the NAPLEX examination in another licensing jurisdiction shall make arrangements for the National Association of Boards of Pharmacy to send verification of examination scores directly to the department.

(d) An applicant for licensure by examination must submit an application under 12 AAC 52.070 and be approved under 12 AAC 52.092 before sitting for examination under this section.

(e) An applicant who has failed the Alaska pharmacy jurisprudence examination specified in (f) of this section may not retake the examination for at least 30 days.

(f) The Multistate Pharmacy Jurisprudence Examination administered by the National Association of Boards of Pharmacy (NABP) is the examination adopted by the board as the Alaska pharmacy jurisprudence examination. An applicant shall satisfy all other license requirements within one year after passing the Alaska pharmacy jurisprudence examination or retake the examination.

(g) An applicant applying for a pharmacy license by examination shall make application within one year of successfully passing the NAPLEX. An applicant applying more than one year after passing the NAPLEX shall retake the NAPLEX or apply for a pharmacy license under AS 08.80.145.

Authority: AS 08.01.065 AS 08.80.005 AS 08.80.030 AS 08.80.110 AS 08.80.120 AS 08.80.150 AS 08.80.160

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements set out in (c) of this section has demonstrated the qualifications for a pharmacist license by reciprocity. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license by reciprocity will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by reciprocity.

(b) An applicant for licensure under this section must show that the licensing jurisdiction where the applicant is licensed as a pharmacist allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in AS 08.80.145. A licensing jurisdiction that is a member of the National Association of Boards of Pharmacy meets the licensing jurisdiction reciprocity requirements of AS 08.80.145.

(c) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records related to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) either

(A) verification that, within the one-year period immediately preceding application for a license in this state, the applicant completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080; the verification must be sent directly to the department from the agency where the hours of internship or experience were completed; or

(B) verification that the applicant has engaged in the practice of pharmacy for at least one year in another licensing jurisdiction;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(8) verification that the applicant is currently licensed as a pharmacist in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(9) if the licensing jurisdiction in which the applicant is licensed as a pharmacist is a member of the National Association of Boards of Pharmacy, a copy of the applicant's Official Application for Transfer of Pharmaceutic Licensure, sent directly to the department from the National Association of Boards of Pharmacy;

(10) verification of the present status of the applicant's license in each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist.

(d) An applicant for licensure under this section who has not taken the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090 is approved to sit for that examination if the applicant has submitted the documents required under (c)(1) – (6) and (8) – (10) of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52.100. TEMPORARY PHARMACIST LICENSE. (a) The board will issue a temporary pharmacist license to an applicant for licensure if the applicant

(1) submits a completed application for licensure;

(2) provides certified evidence of meeting the requirements in AS 08.80.110, AS 08.80.145, and this chapter;

(3) repealed 2/26/2000;

(4) provides for the National Association of Boards of Pharmacy (NABP) to notify the board that the applicant has submitted a preliminary application to NABP for license transfer;

(5) pays the application fee, pharmacist license fee, and temporary license fee required in 12 AAC 02.310;

(6) passes the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above;

(7) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely; and

(8) submits a verification of a current license in good standing to practice in another state or other jurisdiction with licensing requirements at least equivalent to those of this state.

(b) An applicant whose application for permanent licensure as a pharmacist has been denied by the board is not eligible to receive a temporary license.

(c) A temporary license is valid for 90 days. For good cause shown to the board's satisfaction, the board will extend the temporary license for an additional period not to exceed 60 days.

(d) A temporary license is not renewable.

(e) An individual may not receive more than one temporary license.

Authority: AS 08.80.005 AS 08.80.145 AS 08.80.150
AS 08.80.030

12 AAC 52.110. EMERGENCY LICENSURE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN. (a) If the board determines that an emergency exists requiring the provision of licensed coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, the board may issue an emergency pharmacist, pharmacy intern, or pharmacy technician permit to an applicant who

(1) submits a completed application on a form provided by the department;

(2) pays the emergency permit fee required in 12 AAC 02.310;

(3) submits verification on a form provided by the department that the applicant is currently licensed in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(4) repealed 10/31/2019; and

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

(b) An emergency permit under (a) of this section is nonrenewable, and is valid for 90 days or until the emergency circumstances no longer exist, whichever is shorter.

(c) Repealed 11/19/2020.

(d) In an urgent situation, the board may issue an emergency courtesy license to practice as a pharmacist, pharmacy intern, or pharmacy technician to an applicant who meets the requirements of this section. The board may restrict the license to only those services required to respond to the urgent situation. The licensee may not practice as a pharmacist, pharmacy intern, or pharmacy technician outside the scope of the limited purpose for which the emergency courtesy license is issued.

(e) An applicant for an emergency courtesy license under this section must submit to the department a completed application on a form provided by the department. A complete application includes the applicable application and licensing fees established in 12 AAC 02.105.

(f) An emergency courtesy license issued under this section is valid for the period specified by the board and may not exceed 120 consecutive days. An emergency courtesy license may be renewed for one additional period specified by the board, not to exceed 120 consecutive days.

(g) The board will not issue, and an emergency courtesy license holder may not use, an emergency courtesy license as a substitute for a temporary license or other license required under AS 08.80.

(h) While practicing under an emergency courtesy license issued under this section, the holder of the emergency courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(i) The board may refuse to issue an emergency courtesy license for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.

(j) In this section, "urgent situation" means a health crisis requiring an increased availability of pharmacists, pharmacy interns, or pharmacy technicians.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license.

(b) The following checklist is established by the board for review by staff of an application for a pharmacist intern license. A pharmacist intern license will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the application fee and the pharmacist intern license fee established in 12 AAC 02.310;

(3) has

(A) enrolled in a college of pharmacy accredited by the ACPE; or

(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act); and

(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

(c) A pharmacist intern license is valid for two years and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of (b)(1) and (2) of this section.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state;

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for an out-of-state pharmacy registration. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive an out-of-state pharmacy registration will not be issued a registration unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that registration.

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(1) applies on an application provided by the department that includes

(A) the company name and owner name;

(B) the pharmacy name;

(C) the location of the facility;

(D) a mailing address and telephone number;

(E) a toll free number accessible by patients in this state;

(F) the federal employer identification number;

(G) the names of all partners or corporate officers;

(H) the name, address, and telephone number for pharmacist-in-charge;

(I) the names of all pharmacists working in the facility;

(J) completion of the professional fitness section of the application; and

(K) the name of the appointed registered agent;

(2) pays the application fee and the out-of-state pharmacy registration fee established in 12 AAC 02.310;

(3) submits a certified true copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an inspection report or self-inspection report completed within the last two years.

(c) A pharmacy located outside of the state that ships, mails, or delivers prescription drugs into the state more than twice during a 12-month period shall register with the board.

(d) In AS 08.80.158(b)(4), "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's policies and procedures.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.140. PHARMACY TECHNICIAN LICENSE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy technician license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacy technician license will not be

issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacy technician license.

(b) The following checklist is established by the board for review of an application for a pharmacy technician license; a pharmacy technician license will be issued to an applicant who

(1) submits a completed form for application, including

(A) the applicant's name, mailing address, and telephone number; and

(B) the applicant's date of birth that shows the applicant is at least 18 years old;

(2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;

(3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued;

(4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and

(5) pays the application fee and the pharmacy technician license fee established in 12 AAC 02.310.

(c) A pharmacy technician license expires on June 30 of even-numbered years and may be renewed.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.150. PROOF OF LICENSURE FOR INDIVIDUAL PHARMACISTS WORKING FOR TRIBAL HEALTH PROGRAMS. (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not licensed by the board must provide the board notice that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30 days after an individual begins working at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(A) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450 – 458ddd-2 (Indian Self-Determination and Education Assistance Act); or

(B) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor.

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption does not extend to services provided to non-tribal health programs. In addition, an out-of-state licensed pharmacist working outside the scope of the individual's contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80.

Authority: AS 08.80.003 AS 08.80.005 AS 08.80.030

ARTICLE 2.
PERSONNEL.

Section

12 AAC 52.200. PHARMACIST-IN-CHARGE. (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) establishing policies and procedures for pharmacy operations;

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals;

(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and

(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department and paying the applicable fees established in 12 AAC 02.105(3).

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.160 AS 08.80.330

12 AAC 52.210. PHARMACIST DUTIES. Except as provided in 12 AAC 52.220 and 12 AAC 52.235, the following duties may be performed only by a pharmacist:

(1) receiving an oral prescription drug order from a practitioner or authorized agent of a practitioner;

(2) consulting with a prescriber regarding a patient or prescription;

(3) interpreting a prescription drug order;

(4) determining the product required for a prescription;

(5) interpreting data in a patient medication record system;

(6) assuming the responsibility for a filled prescription;

(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system; and

(8) administering a prescription drug order in accordance with the practitioner's order.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.220. PHARMACIST INTERNS. (a) A pharmacist intern may not represent that the pharmacist intern is a pharmacist. Only a person licensed by the board as a pharmacist intern may take, use, or exhibit the title of pharmacist intern or any other similar term.

(b) Except as provided in (c) of this section, a pharmacist intern may perform any duty of a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

(c) A pharmacist intern may not sign or initial any document that is required to be signed or initialed by a pharmacist unless the supervising pharmacist also signs or initials the document.

(d) A pharmacist intern shall file with the board a report of work experience on a form provided by the department within 30 days of completion or termination of an internship in the practice of pharmacy required under 12 AAC 52.080.

(e) A pharmacist supervising a pharmacist intern

(1) must be licensed as a pharmacist and be in good standing with the board;

(2) shall provide direct supervision to an intern during professional activities throughout the entire period of the internship;

(3) repealed 4/3/2020;

(4) is responsible for the work of the pharmacist intern;

(5) may supervise more than one pharmacist intern; more than one pharmacist intern may not dispense simultaneously under the direct supervision of the same supervising pharmacist.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110 AS 08.80.116 AS 08.80.410

12 AAC 52.230. PHARMACY TECHNICIANS. (a) The following persons must be licensed as a pharmacy technician:

(1) an individual who assists in performing manipulative, nondiscretionary functions associated with the practice of pharmacy; and

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy.

(b) A pharmacy technician shall work under the direct supervision of a person who is licensed as a pharmacist.

(c) Except as provided in 12 AAC 52.235, a pharmacy technician may not perform any of the duties listed in 12 AAC 52.210.

(d) An individual working as a pharmacy technician shall wear an identification badge that shows the individual's name and identifies the individual as a pharmacy technician.

(e) Before an individual may regularly perform the tasks of a pharmacy technician, the individual shall complete training required by the pharmacist-in-charge. Duties performed by the pharmacy technician must be consistent with the training the pharmacy technician has received.

(f) If a pharmacy technician will assist in the preparation of sterile pharmaceuticals, including parenteral medications, the pharmacy technician must have completed a minimum of 40 hours of on-the-job training in the preparation, sterilization, aseptic technique, and admixture of parenteral and other sterile pharmaceuticals before the pharmacy technician may regularly perform those tasks.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.235. PHARMACY TECHNICIAN WITH NATIONAL CERTIFICATION. (a) A pharmacy technician who holds a national certification may, at the direction of the pharmacist on duty and under the direct supervision of that pharmacist,

(1) perform a final check of and distribute a non-controlled substance prescription if

(A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination of substitution;

(B) the pharmacy uses a bar code scanning and verification system that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label;

(C) the pharmacy uses software that displays the image or graphical description of the correct drug being verified; however, if there is any deviation between the image or graphical description and the actual product being distributed, a pharmacist must review and dispense the order; and

(D) each prescription distributed is electronically verified and the date and quantity distributed is documented in the patient record;

(2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500; or

(3) clarify or obtain missing information from the practitioner or the practitioner's authorized agent on a non-controlled substance prescription drug order.

(b) Prescription drug order information clarifications under (a)(3) of this section must have the following information documented on the prescription drug order:

(1) the result of the clarification;

(2) the initials of the pharmacy technician who holds a national certification;

(3) the name of the practitioner or authorized agent that the pharmacy technician spoke to; and

(4) the date of the call.

(c) A pharmacy technician who holds a national certification may not sign or initial any document that is required to be signed or initialed by a pharmacist.

(d) In this section, "bar code scanning and verification system" means any technology that scans the bar code on a manufacturer drug container to ensure that the product being distributed matches the expectation of what was prescribed and inputted into the dispensing software.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY. (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.

(b) A written protocol must include

(1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;

(2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;

(3) the time period during which the written protocol will be in effect, not to exceed two years;

(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including

(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and

(B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;

(5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;

(6) a list of the specific types of patients eligible to receive services under the written protocol;

(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months;

(8) a plan for providing the authorizing practitioners with each patient record created under the written protocol;

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.

(d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

(h) This section does not apply to participation, by a pharmacist practicing in an institutional facility, in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

(i) A signed copy of the approved collaborative practice application and protocols must remain at the pharmacy location at all times.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.250. JOB SHADOWING IN PHARMACY. (a) A pharmacist-in-charge or job shadowing preceptor of a pharmacy may allow job shadowing by a student in the pharmacy only as specified in this section.

(b) Before a student begins a job shadowing program under this section, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board, which includes the names of the pharmacy, the participating student, and the pharmacist-in-charge or job shadowing preceptor. The student and the pharmacist-in-charge or preceptor, shall sign the form. The parent or guardian of the student shall also sign the form if the student is less than 18 years of age.

(c) The pharmacist-in-charge or, if applicable, the job shadowing preceptor shall familiarize the student with the confidentiality requirements of 45 C.F.R., Parts 160 and 164 (HIPAA) and ensure compliance with this section and the relevant sections of AS 08.80 and this chapter.

(d) A pharmacist-in-charge or job shadowing preceptor may not allow

(1) a student in a job shadowing program to

(A) receive any remuneration or other compensation;

(B) perform job shadowing for more than 50 hours;

(C) perform any functions reserved for licensed, certified, or registered pharmacy personnel;

(2) a ratio of job shadowing student to pharmacist-in-charge or job shadowing preceptor other than one to one.

(e) After completion of the job shadowing program by a student, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board where the pharmacist-in-charge or job shadowing preceptor provides the date and time in hours student was present and job shadowing in the pharmacy, any patient counseling observations, problems that may have occurred during job shadowing. The job shadowing documentation form must be kept in the pharmacy record for at least two years after the job shadowing program has been completed by that student.

(f) In this section,

(1) "job shadowing" means for educational purposes and through observation only, the observation by a student of the functions and duties of a pharmacy and pharmacy staff with the intended purpose of giving the student an opportunity to observe career possibilities available in the field of pharmacy;

(2) "job shadowing preceptor" means a licensed pharmacist, other than the pharmacist-in-charge, designated by the pharmacist-in-charge to supervise a student while that student is job shadowing;

(3) "student" means a person currently enrolled in a high school or post-secondary education program.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

Editor's note: The job shadowing documentation form required by 12 AAC 52.250 may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, P.O. Box 110806, Juneau, AK 99811-0806; phone: (907) 465-2589; or the division's website at http://www.commerce.state.ak.us/occ/ppha.htm.

ARTICLE 3.
LICENSE RENEWAL AND CONTINUING EDUCATION REQUIREMENTS.

Section

12 AAC 52.300. LICENSE RENEWAL. (a) Pharmacy, wholesale drug distributor, and drug room licenses expire on June 30 of even-numbered years.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, or drug room license shall submit

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) a completed self-inspection of the premises questionnaire on a form provided by the department.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;

(4) repealed 4/3/2020.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157
AS 08.80.005 AS 08.80.147 AS 08.80.165

12 AAC 52.310. REINSTATEMENT OF AN EXPIRED PHARMACIST OR PHARMACY TECHNICIAN LICENSE. (a) If a pharmacist's or pharmacy technician's license has expired for any reason, that pharmacist or pharmacy technician may not practice pharmacy until the license is reinstated by the board.

(b) The board will reinstate a pharmacist or pharmacy technician license that has been expired less than two years if the applicant submits

(1) a completed renewal application;

(2) any applicable license renewal fees required in 12 AAC 02.310;

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) for a licensing period that begins on or after July 1, 2006, a completed jurisprudence questionnaire prepared by the board, covering the provisions of AS 08.80 and this chapter.

(c) The board will reinstate a pharmacist license that has been expired two years or more if the applicant

(1) submits a completed application for reinstatement on a form provided by the department;

(2) pays any applicable license renewal fees required in 12 AAC 02.310 for the entire period the license has been expired;

(3) repealed 5/5/2000;

(4) submits evidence of completion of all continuing education requirements in 12 AAC 52.320 - 12 AAC 52.350 that would have been required to maintain a current license for the entire period the license has been expired;

(5) qualifies by

(A) retaking and passing the examinations required in 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired, and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.

(d) Repealed 8/1/2014.

(e) A pharmacy technician license that has been expired for two years or more will not be reinstated.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005 AS 08.80.147

12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacist license shall certify having completed 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding license period.

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) An individual who is applying for renewal of a pharmacist license for the first time shall certify having completed one half of the continuing education requirements in (a) of this section for each complete 12 month period that the applicant was licensed during the concluding license period.

(d) An applicant for reinstatement of a pharmacist license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

(e) A pharmacist administering a vaccine or related emergency medication under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.325. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacy technician license shall certify that, during the concluding licensing period, the applicant

(1) completed 10 contact hours of continuing education accepted by the board under 12 AAC 52.340; or

(2) obtained initial certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB).

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) Instead of complying with the continuing education requirements in (a) of this section, an applicant for renewal of a pharmacy technician license for the first time may

(1) verify in an affidavit, on an application for renewal, that the applicant has read the state statutes and regulations compiled by the board; and

(2) submit an affidavit, signed by the pharmacist-in-charge, verifying the applicant's pharmacy technician training in accordance with 12 AAC 52.230.

(d) An applicant for reinstatement of a pharmacy technician license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005

Editor's note: Information regarding certification with the Pharmacy Technician Certification Board described in 12 AAC 52.325 may be obtained from the Pharmacy Technician Certification Board, 1100 15th Street, NW, Suite 703, Washington, DC 20005-1707, phone: (202) 429-4120 or at PTCB's website at www.ptcb.org. The Alaska Pharmacists Association, 203 West 15th Avenue, #100, Anchorage, AK 99501, phone: (907) 563-8880, email: akphrmcy@alaska.net also provides certification information.

12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE. An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.165

12 AAC 52.340 APPROVED PROGRAMS. (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE that results in a continuing education certificate showing the date of the course and the ACPE Universal Activity Number associated with the program;

(2) cardiopulmonary resuscitation(CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD. (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section,

the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

Authority: AS 08.80.005 AS 08.80.165 AS 08.80.261
AS 08.80.030

ARTICLE 4.
GUIDELINES FOR PHARMACIES AND PHARMACISTS.

Section

12 AAC 52.400. GENERAL GUIDELINES FOR PHARMACIES. A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, "*Facility Standards for Pharmacies,*" dated November 2016, and incorporated by reference in this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.410. CARE OF DRUG STOCKS AND DEVICES. (a) A drug or device that has exceeded its expiration date shall be removed from stock and quarantined until properly disposed of in accordance with 12 AAC 52.560.

(b) A pharmacist may not dispense a drug or device beyond the expiration date on the drug or device.

(c) All drugs and devices on shelves or display for sale shall be protected against contamination, deterioration, and adulteration.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.420. SECURITY. (a) Each pharmacist, while on duty, is responsible for the security of the pharmacy, including effective control against theft or diversion of drugs.

(b) The pharmacist-in-charge is responsible for compliance with all prescription department security requirements.

(c) All drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) The prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(e) A pharmacy with service hours differing from the remainder of the business establishment must have a telephone number that is separate from the remainder of the business establishment.

(f) Prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

(g) A pharmacist shall provide adequate security for prescription records to prevent unauthorized access to confidential health information.

(h) In this section, "prescription department" means the area of the pharmacy where prescription drugs are stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.315
AS 08.80.030

12 AAC 52.423. REMOTE PHARMACY LICENSE. (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12AAC 02.310; and

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

(1) it is able to comply with the requirements of 12 AAC 52.425; and

(2) there is no access to a non-remote pharmacy within ten road miles of the proposed remote pharmacy site unless the non-remote pharmacy is prevented by federal law from providing pharmacy services to all the individuals within the ten road miles.

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY. (a) Only a pharmacist employed by a central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist located in this state. The pharmacist-in-charge of a remote pharmacy may supervise one or more remote pharmacies.

(b) Before a pharmacist employed by a central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

(1) still image capture;

(2) real time link;

(3) store and forward.

(c) A remote pharmacy must be

(1) staffed by a pharmacist, pharmacy technician, or pharmacy intern; and

(2) operated under the direct supervision of a pharmacist.

(d) A remote pharmacy must be secured to prevent unauthorized access at all times when a pharmacist is not available to provide direct supervision to that location.

(e) Drugs may be shipped to a remote pharmacy from the central pharmacy or a wholesale distributor. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped.

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must have access to the records of the prescriptions dispensed by the remote pharmacy.

(g) The prescription label of a prescription drug dispensed by a remote pharmacy must meet the requirements of 12 AAC 52.480.

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the remote pharmacy. A prescription drug may not be dispensed by a remote pharmacy until a pharmacist employed by the central pharmacy has verified the finished prescription product through the telepharmacy system.

(i) A pharmacist must conduct a physical inventory at each remote pharmacy location at least annually. The record of the inventory must be

(1) kept both at the central pharmacy and the remote pharmacy; and

(2) distinguishable from the inventory of the central pharmacy and other remote pharmacies.

(j) Repealed 10/31/2019.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.430. GUIDELINES RELATING TO STERILE PHARMACEUTICALS. A pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals shall adhere to the guidelines established by the board in the pamphlet titled, "*Sterile Pharmaceuticals,"* dated February 2008, and incorporated by reference in this section.

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.430, *"Sterile Pharmaceuticals"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.440. GUIDELINES RELATING TO COMPOUNDING PRACTICES. A pharmacy or pharmacist that compounds drugs shall adhere to the guidelines established by the board in the pamphlet titled, "*Compounding Practices,"* dated February 2008, and incorporated by reference in this section

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.440, *"Compounding Practices"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.443. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACY. (a) A requesting pharmacy in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacy to participate in shared pharmacy services if the pharmacy establishes

(1) that the pharmacy has a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

(2) that the pharmacy is able to comply with the requirements of 12 AAC 52.445;

(3) that the pharmacy either

(A) is owned by the same owner as the filling pharmacy with which pharmacy services are to be shared; or

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligation of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(4) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST. (a) A requesting pharmacist in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacist to participate in shared pharmacy services if the requesting pharmacist establishes

(1) that the pharmacist

(A) has a current in-state pharmacy license issued under AS 08.80 and this chapter;

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligations of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(C) is able to comply with the requirements of 12 AAC 52.445; and

(2) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.445. SHARED PHARMACY SERVICES. (a) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall use an identifier on the prescription container that identifies prescriptions to be filled at a filling pharmacy or by the filling pharmacist. The requesting pharmacy or requesting pharmacist shall notify the patient or the patient's agent that the patient's prescription order may be processed or filled by another pharmacy or pharmacist, and shall identify the filling pharmacy or filling pharmacist. If the requesting pharmacy is part of a network of pharmacies under common ownership, and the prescription order may be processed or filled at any of the pharmacies in the network, the requesting pharmacy shall notify the patient of this. Notice under this subsection may be provided through an initial written notice to the patient or the patient's agent, or through the use of a sign prominently displayed in the requesting pharmacy or in the public portion of the office of the requesting pharmacist.

(b) Except as provided in (c) of this section, if a filling pharmacy or filling pharmacist delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy or filling pharmacist shall provide, on the prescription container or on a separate sheet delivered with the prescription container,

(1) the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist; and

(2) a statement that conveys to the patient or patient's agent the following information: "Written information about this prescription has been provided for you; please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at [insert the filling pharmacist or filling pharmacy's telephone numbers]."

(c) The requirements of (b) of this section do not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(d) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall

(1) maintain manual or electronic records identifying, individually for each order processed, filled, or dispensed, the name, initials, or identification code of each pharmacist responsible for the final verification of dispensing; those records must include descriptions of actions taken in interpretation of the order, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, and refill authorization functions performed at that pharmacy or by that pharmacist;

(2) report to the board as soon as practical the results of any license disciplinary action taken by a regulatory agency in another licensing jurisdiction involving a pharmacy or pharmacist participating in shared pharmacy services;

(3) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy or by that pharmacist;

(4) provide for adequate security to protect the confidentiality and integrity of patient information;

(5) provide for inspection of any required record or information no later than 72 hours after any request by the board or its designee.

(e) Each pharmacy participating in shared pharmacy services, if a

(1) requesting pharmacy, shall have a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

(2) filling pharmacy, shall either

(A) have a current in-state pharmacy license issued under AS 08.80.157 and this chapter; or

(B) be registered as an out-of-state pharmacy under AS 08.80.158 and this chapter.

(f) Each participant in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services. Each participant is required to maintain only those portions of the joint policies and procedures that relate to that participant's operations. The policies and procedures must

(1) outline the responsibilities of each participant;

(2) include a list that contains

(A) each pharmacy participating in shared pharmacy services, and each pharmacist acting independently of a pharmacy and participating in shared pharmacy services;

(B) the name, address, and telephone number of each of those participants; and

(C) the license numbers for all licenses held by each of those participants; and

(3) address

(A) patient notification that meets the requirements of this section;

(B) the adequate protection of the confidentiality and integrity of patient information;

(C) dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;

(D) the maintenance of manual or electronic records that meet the requirements of this section;

(E) compliance with federal and state laws; and

(F) the operation of a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(g) Nothing in this section prevents an individual pharmacist licensed in this state who is employed by or working under a contract with a pharmacy, or prevents a licensed pharmacy intern or pharmacy technician working under the supervision of that licensed pharmacist, from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription order in compliance with AS 08.80 and this chapter if

(1) the pharmacy has established controls to protect the privacy and security of confidential records; and

(2) the pharmacist, pharmacy intern, or pharmacy technician does not duplicate, download, or remove data from the pharmacy's electronic database.

(h) A pharmacist working independently outside of the state may participate in shared pharmacy services with an institutional pharmacy in this state if the pharmacist holds

(1) a current license as a pharmacist issued under AS 08.80 and this chapter; and

(2) a current license to practice as a pharmacist issued by the licensing jurisdiction where the pharmacist is working.

(i) The pharmacist-in-charge of the requesting pharmacy must ensure compliance with the applicable requirements of AS 08.80 and this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.158
AS 08.80.030

12 AAC 52.446. SHARED PHARMACY SERVICES DURING EMERGENCY. (a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy services without applying for approval under 12 AAC 52.443 and 12 AAC 52.444.

(c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient’s agent, the filling pharmacy or filling pharmacist or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container, the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.

(d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall maintain manual or electronic records identifying, individually for each order processed, filled or dispensed,

(1) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and

(2) the patient, date, drug, strength, directions, and quantity dispensed.

(f) A pharmacy participating in shared pharmacy services that distributes prescription drug orders under 12 AAC 52.235 using a pharmacy technician who holds a national certification shall maintain manual or electronic records identifying, individually for each order processed, filled, or distributed

(1) the name, initials, or identification code of each pharmacy technician who holds a national certification; and

(2) the patient, date, drug, strength, directions, and quantity distributed.

(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

ARTICLE 5.
PHARMACY PRACTICE STANDARDS.

Section

12 AAC 52.450. PRESCRIPTION DRUG ORDER RECORDS. (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug orders by

(1) keeping the original hard copy prescription drug order presented by a patient;

(2) keeping a plain paper version of the prescription drug order received by facsimile or digital electronic transmittal;

(3) keeping a prescription drug order put into writing either manually or electronically by the pharmacist; or

(4) electronically storing and maintaining the prescription drug order in a readily retrievable format.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.460. PRESCRIPTION DRUG ORDER INFORMATION. (a) Before a pharmacist may fill a prescription drug order, the pharmacist shall obtain the following information:

(1) name of the patient or, if the prescription drug order is for an animal, species of the animal and name of the owner;

(2) address of the patient unless the prescription drug order is for a noncontrolled substance and the address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as a patient medication record;

(3) name and, if the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;

(4) name and strength of the drug prescribed;

(5) quantity prescribed;

(6) directions for use;

(7) date of issue;

(8) refills authorized, if any;

(9) if a written or hard copy prescription drug order, the prescribing practitioner's handwritten, digital, electronic, or stamped signature;

(10) if a prescription drug order is received by the pharmacy as a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped signature, or authorized agent's signature; and

(11) if the prescription drug order is signed by an authorized agent, the name of the prescribing practitioner.

(b) At the time of dispensing, a pharmacist shall add the following information to the prescription drug order:

(1) unique identification number of the prescription drug order;

(2) initials or identification code of the dispensing pharmacist;

(3) quantity dispensed, if different from the quantity prescribed;

(4) date of dispensing, if different from the date of issue;

(5) if the drug was prescribed by generic name or if an equivalent drug product other than the one prescribed was dispensed, for the drug product actually dispensed, at least one of the following:

(A) the name of the drug product’s manufacturer or distributor;

(B) the national drug code number;
(C) the short name code; or
(D) the trade name.

(c) After oral consultation with the prescribing practitioner, a pharmacist may add the following information to schedule II controlled substance prescriptions:
(1) date of issue of the prescription;
(2) address of the patient;
(3) strength of the drug prescribed;
(4) drug dosage form;
(5) drug quantity prescribed;
(6) directions for use;
(7) DEA registration number.

(d) After oral consultation with the prescribing practitioner, a pharmacist may modify the types of information described in (c)(2) – (7) of this section. However, any modification to the information concerning drug quantity must be limited to strength of the drug prescribed and may not result in an increase in the original total dosage prescribed.

(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.465. CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDERS. A prescription drug order for a schedule II controlled substance may be partially filled if prescribed for

(1) a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 C.F.R. 1306.13; or

(2) a patient who is not terminally ill or residing in a long term care facility if

(A) the partial fill is requested by the patient or the practitioner that wrote the prescription;

(B) the total quantity dispensed in all partial filling does not exceed the total quantity prescribed;

(C) each partial fill is electronically documented in the patient record;

(D) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and

(E) each partial fill only occurs at the pharmacy where the original prescription order is on file.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.470. REFILLS. (a) Repealed 4/3/2020.

(b) Repealed 4/3/2020.

(c) Each time a prescription drug order refill is dispensed, the pharmacist or pharmacist intern shall record the quantity and date of the dispensing.

(d) A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the

(1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills; and

(2) drug is not a federal or state scheduled controlled substance.

(e) To indicate that an increased supply may not be dispensed under this section, a prescriber may indicate "no change to quantity", or words of similar meaning, on the prescription drug order.

(f) Nothing in this section requires a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including a state program or state employer, to provide coverage for a drug in a manner inconsistent with a beneficiary's plan benefit.

(g) Under (d) of this section, if the total quantity of a drug or device to dispense on an existing, chronic, non-controlled substance prescription drug order has been exhausted and the pharmacist is unable to reach the practitioner, a pharmacist or pharmacist intern may continue to dispense a quantity not to exceed a 120-day supply. In this section,

(1) "existing" means the pharmacy has record of a previous prescription drug order or the pharmacist can validate the prescription drug order from another pharmacy or patient labelled product;

(2) "chronic" means a drug that the patient takes regularly, for greater than three months.

(h) Under (g) of this section, the pharmacist must

(1) reduce the patient's prescription drug order to a written prescription drug order using the previously verified prescription drug order information and practitioner name;

(2) document "continuation of therapy", "COT", or words of similar meaning on the prescription drug order; and

(3) file and maintain the prescription in accordance with 12 AAC 52.450.

(i) A pharmacist may not dispense a refill of a prescription drug order for a noncontrolled substance after one year from the date of issue of the original prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.480. LABELING. One or more labels containing the following information shall be affixed to every container in which a prescription drug order is dispensed:

(1) name, address, and phone number of the dispensing pharmacy;

(2) unique identification number of the prescription drug order;

(3) date the prescription drug order is dispensed;

(4) initials, which may be handwritten, of the dispensing pharmacist or pharmacist intern;

(5) name of the prescribing practitioner;

(6) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;

(7) directions for use;

(8) quantity dispensed;

(9) appropriate ancillary instructions or cautions;

(10) if the prescription drug order is for a schedule II-V controlled substance, the statement, "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(11) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner;

(12) the accepted generic drug name and strength of the drug dispensed; if the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient's agent.

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

12 AAC 52.490. PRESCRIPTIONS BY ELECTRONIC TRANSMISSION. (a) Legend drug, device, and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws. A pharmacist or pharmacist intern may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

(1) name, address, and telephone number of the prescribing practitioner;

(2) electronic signature or manual signature of the prescribing practitioner;

(3) the information required in 12 AAC 52.460(a)(1) - (8); and

(4) any other information required by federal law.

(b) A pharmacist may dispense a prescription that has been received electronically.

(c) The system for electronic transmission of prescriptions must address the following:

(1) patient's choice of pharmacy; the system may not restrict the patient's choice of pharmacy;

(2) security of the system; the system must have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information; the system must include

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other applicable equipment from an unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control, and audit access to confidential patient information; and

(D) processes to prevent unauthorized access to the prescription information when transmitted electronically;

(3) confidentiality of patient information; the system must maintain the confidentiality of patient information consistent with state and federal laws;

(4) authentication; to be valid prescriptions transmitted by an authorized prescriber or the prescribing practitioner's authorized agent from computer to a facsimile machine or from computer to computer must use an electronic signature; the prescribing practitioner's system must authenticate the sender's authority and credentials to transmit a prescription to a pharmacy and

(A) the prescribing practitioner's system must provide an audit record of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;

(B) the right of the board to access the prescribing practitioner's electronically transmitted prescriptions for purposes of investigations;

(5) a prescribing practitioner's system that utilizes intermediaries in the electronic communication of prescriptions to pharmacies is responsible to ensure that the contracts with the intermediaries require security measures that are equal to or better than those provided by this section and prohibit the modification of a record of a prescription after it has been transmitted by the prescribing practitioner to the pharmacist;

(6) if a paper copy prescription that is generated by the pharmacist or pharmacy technician from the electronic prescription system is printed, an electronic signature may be substituted for a manual signature;

(7) the system must maintain the integrity and confidentiality of patient information transmitted electronically for its system as required by this chapter, other state law, and federal law.

(d) In this section,

(1) "electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription;

(2) "electronic transmission of prescriptions" means the communication from an authorized prescribing practitioner or the prescribing practitioner's authorized agent to a pharmacy of the patient's choice, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with this section, other state law, and federal law;

(3) "security" means a system to maintain the confidentiality and integrity of prescription information, including

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other pertinent equipment from unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control and audit access to confidential patient information; and

(D) processes for its system to prevent unauthorized access to the prescription information when transmitted electronically.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER. (a) For the purpose of dispensing a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. The transfer must be communicated directly between two licensed pharmacists.

(c) Original prescription drug order information for noncontrolled substances may be transferred verbally, electronically, or by means of facsimile between pharmacies without limitation up to the number of originally authorized refills.

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

(1) repealed 4/3/2020;

(2) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);

(3) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information shall record the following information:

(A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information;

(B) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the prescription drug order information;

(C) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(D) the date of the transfer;

(4) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the transferred prescription drug order information shall record the following information:

(A) the original date of issue;

(B) the original unique identification number of the prescription;

(C) the quantity of drug or device remaining;

(D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and

(E) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order.

(e) A pharmacy using an automated data processing system shall meet the same requirements for a manual prescription drug order transfer listed in (d) of this section.

(f) If two or more pharmacies use a common electronic database for prescription record keeping, prescription drug orders may be refilled at any of the pharmacies using the common electronic database if provisions are made

(1) for an audit trail that documents the location of each filling; and

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.510. SUBSTITUTION. (a) A pharmacist or pharmacist intern may dispense an equivalent drug product or interchangeable biological product instead of the prescribed drug if

(1) the prescribing practitioner does not indicate on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording indicating that the practitioner does not want it substituted;

(2) the patient is notified and consents to the substitution;

(3) repealed 10/31/2019; and

(4) for the drug product actually dispensed, the pharmacy record contains one of the following:

(A) the drug product's manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the term "equivalent drug product" or "interchangeable biological product" is defined in AS 08.80.480.

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product if there is nothing on the prescription drug order from the prescribing practitioner that indicates that the practitioner wants only the substituted product dispensed.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.520. CUSTOMIZED PATIENT MEDICATION PACKAGE (PATIENT MED-PAK). (a) Instead of dispensing one or more prescribed drug products in separate containers, a pharmacist may, with the written consent of the patient, patient's caregiver, or prescribing practitioner, provide a customized patient medication package or patient med-pak.

(b) A patient med-pak is a series of containers prepared by a pharmacist for a specific patient containing one or more prescribed solid oral dosage forms and designed or labeled to indicate the day and time, or period of time, when the contents within each container are to be taken.

(c) The pharmacist shall prepare a label for a patient med-pak that includes

(1) the name of the patient;

(2) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for the drug products in the patient med-pak;

(3) the name, strength, physical description or identification, and total quantity of each drug product in the patient med-pak;

(4) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product in the patient med-pak;

(5) any other information, statements, or warnings required or appropriate for any of the drug products in the patient med-pak;

(6) the name of the prescribing practitioner of each drug product in the patient med-pak;

(7) the date of preparation of the patient med-pak and the expiration date assigned to the patient med-pak; the expiration date may not be more than 60 days from the date of preparation of the patient med-pak;

(8) the name, address, and telephone number of the pharmacy; and

(9) the initials of the dispensing pharmacist.

(d) If the patient med-pak allows for the removal or separation of the intact containers from the patient med-pak, the pharmacist shall label each individual container of the patient med-pak to identify each of the drug products contained in the patient med-pak.

(e) When preparing a patient med-pak, the dispensing pharmacist shall take into account any applicable compendium requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container in the med-pak and any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(f) In addition to any individual prescription filing requirements, the pharmacist shall make and file a record of each patient med-pak. Each record must contain

(1) the name and address of the patient;

(2) a unique identification number for the patient med-pak itself and a separate, unique, identification number for each of the prescription drug orders for each drug product contained in the patient med-pak;

(3) information identifying or describing the design, characteristics, or specifications of the patient med-pak that is sufficient to prepare an identical patient med-pak for the patient;

(4) the date of preparation of the patient med-pak and the expiration date assigned;

(5) any special labeling instructions; and

(6) the name or initials of the pharmacist who prepared the patient med-pak.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.530. RETURN OR EXCHANGE OF DRUGS. (a) A pharmacy or pharmacist may accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed if

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or the medication was recalled by the manufacturer or the United States Food and Drug Administration; and

(2) the drug is segregated from the normal pharmacy inventory and may not be dispensed.

(b) A pharmacy serving an institutional facility may accept for return or reuse unit dose packages or full or partial multiple dose medication cards if

(1) the pharmacist can readily determine that there has been no entry or attempt at entry to the unit dose package or blister card;

(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the standards of the United States Pharmacopoeia (1995 revision) for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

(3) the drug has not come into the physical possession of the person for whom it was prescribed, and control of the drug is known to the pharmacist to have been the responsibility of a person or persons licensed to prescribe, dispense, or administer drugs; and

(4) the drug labeling or packaging has not been altered or defaced, and the identity of the drug, its strength, lot number, and expiration date are retrievable.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: A copy of the United States Pharmacopoeia may be obtained from the United States Pharmacopoeial Convention, Inc., P.O. Box 560, Williston, VT 05495.

12 AAC 52.540. NOTIFICATION OF THEFT OR SIGNIFICANT LOSS. If a pharmacy is required under 21 U.S.C. 801 - 904 (Controlled Substances Act) to complete DEA Form 106, "Report of Theft or Loss of Controlled Substances," the pharmacist-in-charge shall also send a copy of the completed form to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.550. ADVERTISING. A pharmacy may advertise prescription drug prices if the advertisement contains all of the following information:

(1) proprietary, trade, or generic name of the drug product;

(2) name of the manufacturer or distributor of the drug product;

(3) dosage form and strength of the drug product;

(4) price charged for a specific quantity of the drug product; and

(5) the hours that pharmaceutical services are available from the advertiser.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.560. DESTRUCTION AND DISPOSAL OF DRUGS. (a) A licensed pharmacist may destroy noncontrolled prescription drugs if the drugs are destroyed in a manner that makes the drugs unfit for human consumption.

(b) A drug that is a controlled substance shall be disposed of in accordance with federal statutes and regulations.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.570. DRUG REGIMEN REVIEW. (a) A pharmacist shall perform a drug regimen review, as defined in AS 08.80.480, for each prescription drug order.

(b) If a pharmacist identifies any of the items listed in AS 08.80.480 during the drug regimen review, the pharmacist shall avoid or resolve the problem by consulting with the prescribing practitioner, if necessary.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.580. DATA PROCESSING SYSTEMS. A pharmacy may use an automated data processing system to maintain the records required in AS 08.80 and this chapter if the system

(1) is capable of on-line retrieval of all information required in 12 AAC 52.460, 12 AAC 52.470, and 21 C.F.R. 1306.22, as amended as of February 6, 1997;

(2) is capable of producing an audit trail printout for all dispensing of any specified strength and dosage form of a drug; and

(3) has adequate safeguards to prevent loss of data and reasonable security to prevent unauthorized access to, modification of, or manipulation of patient records.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.585. MANDATORY PATIENT COUNSELING. (a) Before dispensing a prescription for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

(1) the name and description of the prescribed drug;

(2) the dosage and the dosage form;

(3) the method and route of administration;

(4) the duration of the prescribed drug therapy;

(5) any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;

(6) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;

(7) patient techniques for self-monitoring of the drug therapy;

(8) proper storage;

(9) prescription refill information; and

(10) the action to be taken in the event of a missed dose.

(b) A pharmacist shall counsel the patient or the patient's agent face-to-face. If face-to-face counseling is not possible, a pharmacist shall make a reasonable effort to provide the counseling by use of a telephone, two-way radio, or in writing. In place of a pharmacist's own written information regarding a prescribed drug, the pharmacist may use abstracts of the Patient United States Pharmacopoeia Drug Information or comparable information.

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) This section does not require a pharmacist to provide patient counseling when a patient or the patient's caregiver refuses the counseling.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.590. PREPACKAGING OF DRUGS. For the purpose of supplying drugs to a prescribing practitioner, drugs shall be prepackaged in child-resistant containers under the direct supervision of a pharmacist and bear a label that contains

(1) the name, address, and telephone number of the pharmacy;

(2) the name, strength, and quantity of the drug;

(3) the lot number and expiration date of the drug, if not already contained on the unit-of-use or drug packaging;

(4) cautionary information required for patient safety and information; and

(5) the initials of the pharmacist.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

ARTICLE 6.
WHOLESALE DRUG DISTRIBUTORS AND FACILITIES.

Section

12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a wholesale drug distributor

license. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a wholesale drug distributor license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a wholesale drug distributor license.

(b) The board will issue a wholesale drug distributor license to an applicant who

(1) submits a completed, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) provides the name and the resume of the facility manager who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) submits

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; or

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, if the applicant is a wholesale drug distributor located outside of this state.

(c) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (b) of this section; and

(2) be registered with the DEA.

(d) Within 30 days after a change in location, ownership, or facility manager, the new facility manager must

(1) submit the completed change of facility manager form provided by the department;

(2) submit the applicable fees established in 12 AAC 02.105(3); and

(3) meet the requirements of (b)(4) and (6) of this section.

(e) When a wholesale drug distributor ceases operations, the facility manager of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 10 days after the cessation of operations.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.159 AS 08.80.480

12 AAC 52.620. WHOLESALE DRUG FACILITIES. (a) A wholesale drug facility in which drugs are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs must

(1) have storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(2) be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(3) be equipped with an alarm system to detect entry into the wholesale drug facility after business hours;

(4) meet all applicable federal, state, and local building standards;

(5) be secure from unauthorized entry from outside the facility, including having exterior lighting along the outside perimeter of the facility;

(6) restrict entry into areas inside the facility where drugs are stored; entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

(8) be maintained in a clean and orderly condition; and

(9) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) A wholesale drug facility must develop internal security policies, including protection of computer records, to provide reasonable protection against theft or diversion of drugs by personnel.

(c) A wholesale drug facility may not be located in a residence.

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must first verify that the purchaser of the prescription drugs holds a valid license under AS 08.80.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.159 AS 08.80.480

12 AAC 52.625. PERSONNEL REQUIREMENTS; GROUNDS FOR DENIAL OR OTHER DISCIPLINARY ACTION. (a) A wholesale drug distributor shall maintain a roster of all officers, directors, and managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(b) The board will not approve an application for a wholesale drug distributor license unless the designated facility manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159 AS 08.80.480

12 AAC 52.630. DRUG STORAGE. (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements to help ensure that the identity, strength, quality, and purity of the products are not affected.

(b) A wholesale drug distributor shall ensure that a separate quarantine storage area is provided for drugs that are deteriorated, outdated, damaged, misbranded, adulterated, or are in a secondary container that has been opened or the seal of which has been broken.

(c) A wholesale drug distributor shall ensure that appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or handwritten logs are used to document how drugs have been stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES. A wholesale drug distributor shall prepare and follow a written procedure to

(1) handle crisis situations that affect the security or operation of the wholesale drugs facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;

(2) identify, record, report to the board, and correct any error found in an inventory;

(3) ensure that any outdated drug or any drug with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph and is prepared for timely return to the manufacturer or is destroyed;

(4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;

(5) ensure the proper handling and disposal of returned drugs;

(6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary;

(7) ensure the proper handling of a drug recall and a replacement of a drug in accordance with 12 AAC 52.670.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS. (a) A wholesale drug distributor shall ensure that upon receipt of a drug shipment, each outside shipping container is visually examined for identity and damage in order to reduce the acceptance of drugs that are contaminated or unfit for distribution.

(b) A wholesale drug distributor shall ensure that each outgoing shipment of drugs is inspected for identity of the contents and the integrity of the shipping container in order to ensure that the drugs to be shipped were not damaged in storage, held under improper conditions, or likely to receive damage in shipment.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.650. RECORDS AND INVENTORIES. (a) A wholesale drug distributor shall establish and maintain records and inventories of all transactions regarding the receipt, distribution, or disposition of a drug. The records must include the following information:

(1) the source of the drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped;

(2) the identity and quantity of the drug received, distributed, or disposed of; and

(3) the date of receipt and of distribution or other disposition.

(b) The records and inventories required by this section must be made available at a central location for inspection within two working days after a request by an authorized inspector. The records and inventories required by this section must be kept for a period of two years after disposition of the drug.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS. (a) A wholesale drug distributor shall ensure that a drug that is outdated, damaged, deteriorated, misbranded, or adulterated is quarantined and physically separated from other drugs until it is either destroyed or returned to the supplier.

(b) A wholesale drug distributor shall ensure that a drug that has a secondary container that has been opened or used is identified as such, and is quarantined and physically separated from other drugs until the drug is either destroyed or returned to the supplier.

(c) A wholesale drug distributor shall ensure that if the conditions under which a drug has been returned, shipped, or stored cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.670. DRUG RECALLS. A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

(1) a voluntary action on the part of the manufacturer;

(2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or

(3) the replacement of an existing drug with an improved drug or new package design.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.680. INSPECTIONS. A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION. A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159

12 AAC 52.690. SALVAGE AND REPROCESSING. A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.695. PROVISIONS NOT APPLICABLE. The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 – 12 AAC 52.690:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) any of the following transfers of a drug, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee during any 12-consecutive-month period:

(A) the sale of a drug by a retail pharmacy to another retail pharmacy or to a practitioner, or the offer by a retail pharmacy to sell a drug to another retail pharmacy or to a practitioner;

(B) the purchase of a drug by a retail pharmacy or by a practitioner from another retail pharmacy, or the offer by a retail pharmacy or by a practitioner to purchase a drug from another retail pharmacy;

(C) the trade of a drug by a retail pharmacy with another retail pharmacy, or the offer by a retail pharmacy to trade a drug with another retail pharmacy;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.159
AS 08.80.030

12 AAC 52.696. OUTSOURCING FACILITIES. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements of (b) of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) The board will issue an outsourcing facility license to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(c) Within 10 days after a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address must apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility must apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(f) When an outsourcing facility ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the outsourcing facility ceased operations; and

(2) arrangement for the records of the outsourcing facility to be retained for two years.

(g) Outsourcing facility personnel shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) The outsourcing facility must be registered as an outsourcing facility with the United States Food and Drug Administration under Sec. 503b, P.L. 113 – 54 (Drug Supply Chain Security Act).

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

12 AAC 52.697. THIRD-PARTY LOGISTICS PROVIDERS. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b) The board will issue a third-party logistics provider license to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.

(c) Within 10 days after a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department

(d) The facility manager of a third-party logistics provider that has changed its name or physical address must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the third-party logistics provider ceased operations; and

(2) arrangement for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider must permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

ARTICLE 7.
INSTITUTIONAL PHARMACIES.

Section

12 AAC 52.700. INSTITUTIONAL PHARMACIES. Repealed 2/26/2000.

12 AAC 52.710. ABSENCE OF A PHARMACIST FROM AN INSTITUTIONAL PHARMACY. (a) When an institutional pharmacy will be unattended by a pharmacist, the pharmacist-in-charge shall arrange in advance for providing drugs for use within the institutional facility.

(b) When an institutional pharmacy is closed and a drug is required to treat a patient's immediate need and is not available from the drug stock outside of the pharmacy, a person designated by the pharmacist-in-charge and licensed to handle drugs may obtain the drug from the institutional pharmacy. The pharmacist-in-charge is responsible

(1) to record on a suitable form the removal of any drug from the institutional pharmacy by the person designated; the record must show the

(A) patient's name and room number;

(B) name, strength, and amount of the drug;

(C) date and time of removal; and

(D) initials or signature of the person designated who removed the drug from the pharmacy;

(2) when the pharmacy reopens or as soon as is practical, to check the stock container or similar unit dose package of the drug removed; and

(3) to ensure that the quantity of drugs that were removed is only the quantity necessary to sustain the patient until the pharmacy reopens.

(c) If an institutional pharmacy is open and the pharmacist is absent from the pharmacy, but present in the institutional facility, a pharmacy technician may continue to prepare and process drug prescriptions. However, drugs may not be dispensed until the pharmacist has verified the finished prescription product.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.720. EMERGENCY ROOM OUTPATIENT MEDICATIONS. (a) The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug.

(b) A licensed health care provider on emergency room staff may deliver the medications identified on the list of prescription drugs prepared under (a) of this section to a patient receiving emergency outpatient treatment if

(1) the drug is ordered by an authorized prescribing practitioner either in writing or verbally; a verbal order must be transcribed into writing on the patient's record;

(2) the medication is prepackaged in a child-resistant container under the direct supervision of a pharmacist;

(3) the medication bears a label that contains the
(A) name, address, and telephone number of the institutional facility;
(B) name, strength, and quantity of the drug;
(C) cautionary information required for patient safety and information;
(D) lot number and expiration date if not already contained on the unit-of-use packaging or prepackaging; and
(E) initials of the pharmacist;
(4) no more than one prepackaged container of a drug is delivered to a patient unless more than one package is required to sustain the patient until a retail pharmacist is on duty in the community; however, the amount of the controlled substance delivered may not exceed a 72 hour supply; and
(5) labeling of the container is completed by the licensed health care provider before the container is presented to the patient; the container label must include the
(A) name of the patient;
(B) directions for use by the patient;
(C) date of delivery;
(D) identifying number unique to the patient;
(E) name of the prescribing practitioner; and
(F) initials of the licensed health care provider delivering the prepackaged medication.

(c) Prepackaged medications shall be kept in a secure place within the emergency room.

(d) Following delivery of the prepackaged medication to the patient, the licensed health care provider shall document the quantity issued and initial the patient record containing the prescribing practitioner's order.

(e) This section does not apply to the administration of a single dose to a patient.

(f) In this section, "licensed health care provider" means a physician, physician assistant, or mobile intensive care paramedic licensed under AS 08.64; a dentist licensed under AS 08.36; or a nurse licensed under AS 08.68.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL. (a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.

(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 and 12 AAC 52.720. The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.

(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.

(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

ARTICLE 8.
DRUG ROOMS AND FACILITIES WITHOUT A PHARMACY.

Section

12 AAC 52.800. DRUG ROOM LICENSE. (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under 12 AAC 52.010 and 12 AAC 52.020.

(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 AS 08.80.390

12 AAC 52.810. PHARMACIST REQUIRED. An institutional facility described in 12 AAC 52.800(a) must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.820. RESPONSIBILITIES OF THE CONSULTANT PHARMACIST. A pharmacist who, under 12 AAC 52.810, provides consultant pharmacy services shall

(1) provide evaluations and recommendations concerning drug distribution, control, and use;

(2) complete on-site reviews to ensure that drug handling and use procedures conform to AS 08.80, this chapter, and recognized standards of practice;

(3) provide drug information to facility staff and physicians;

(4) plan and participate in the facility's staff development program relating to drug distribution, control, and use;

(5) assist in establishing policies and procedures to control the distribution and administration of drugs; and

(6) document pharmacy services that are provided and maintain the documentation for a period of at least two years.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.830. EMERGENCY DRUG KITS. (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.

(b) The pharmacist who provides or supplies drugs in emergency drug kits shall cooperate with the prescribing practitioners on staff at the institutional facility to determine the identity and quantity of the drugs to be included in the emergency drug kits.

(c) An emergency drug kit must

(1) only contain drugs that are not available from any other source in sufficient time to prevent risk of harm to patients;

(2) only contain drugs that are provided and sealed by a pharmacist;

(3) be stored in a secured area to prevent unauthorized access;

(4) be labeled on the exterior to indicate it is for use only in emergencies as described in this section; and

(5) have a list of the kit's contents posted on or near the kit.

(d) Drugs may be removed from an emergency drug kit only under a valid order from a prescribing practitioner.

(e) When the supplying pharmacist is notified that an emergency drug kit has been opened, the supplying pharmacist shall restock the kit within a reasonable time, not to exceed seven days.

(f) The supplying pharmacist shall label the exterior of an emergency drug kit to indicate the expiration date of the kit's contents. The expiration date of an emergency drug kit is the earliest expiration date of any drug supplied in the kit. When an emergency drug kit expires, the supplying pharmacist shall replace any expired drugs in the kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.840. FIRST DOSE KITS. (a) In addition to the emergency drug kit described in 12 AAC 52.830, an institutional facility described in 12 AAC 52.800 may maintain a first dose kit for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility if the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.

(b) The dispensing or consultant pharmacy for the institutional facility and the medical staff of the institutional facility are responsible for the proper storage, security, and accountability of the first dose kit.

(c) The staff of the dispensing or consultant pharmacy for the institutional facility shall determine jointly with the medical staff of the institutional facility the content and quantity of drugs to be included in the first dose kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.850. EMERGENCY DISTRIBUTION. In an emergency, if a drug is not otherwise available, a drug room may distribute the drug from bulk supplies to a practitioner or a pharmacist for use by a patient outside the facility, under a prescription, until the drug can be otherwise obtained.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.390 AS 08.80.480

ARTICLE 9.
CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section

12 AAC 52.855. REGISTRATION WITH THE PRESCRIPTION DRUG MONITORING PROGRAM CONTROLLED SUBSTANCE PRESCRIPTION DATABASE. (a) A prescriber shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) not later than 30 days after the date of initial licensure or the date of registration with the federal Drug Enforcement Administration (DEA), whichever is later.

(b) A licensed pharmacist practicing in this state shall register with the PDMP. Registration must be completed not later than 30 days after initial licensure if the pharmacist's practice is expected to involve dispensing a schedule II, III, or IV controlled substance under federal law. If not dispensing in this state, a pharmacist shall submit, not later than 30 days after initial licensure, a PDMP dispensation exemption form provided by the board. A pharmacist who submitted a dispensation exemption form shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the department.

(f) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.860. ACCESS TO AND CONDITIONS FOR USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM DATABASE. (a) Access to the PDMP is limited as described in AS 17.30.200(d).

(b) For the purposes in AS 17.30.200(d)(1) of an inquiry under a search warrant, subpoena, or order issued by an administrative law judge or a court,

(1) "personnel of the board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy; and

(2) "personnel of another board or agency" means an employee of this state who is assigned to a board or agency that requires a practitioner to register with the PDMP.

(c) For the purposes of AS 17.30.200(d)(2), "authorized board personnel or contractors" means:

(1) employees of the Department of Commerce, Community, and Economic Development, assigned to the Board of Pharmacy, and providing PDMP data storage or data management services; or

(2) employees of a contractor with this state who are providing PDMP data storage or data management services.

(d) For the purposes of AS 17.30.200(d)(3) and (4), a licensed practitioner or licensed or registered pharmacist authorizing an agent or employee to access the PDMP is responsible for maintaining and terminating the agent or employee's access to the PDMP.

(e) For the purposes of AS 17.30.200(d)(8) and (10), "authorized employee of the Department of Health and Social Services" means an employee of the Department of Health and Social Services (DHSS) for whom that department's commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION. (a) Unless excused from reporting under AS 17.30.200(t), a pharmacist must submit information required under AS 17.30.200(b), if the pharmacist-in-charge is not present.

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily as of the previous submission date.

(c) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(d) For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must submit information correcting the error to the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(f) Unless excused from reporting under AS 17.30.200(t), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP electronically through the website provided by the board.

(g) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER. (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purposes of this section, a pharmacist or practitioner must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner will only dispense controlled substances as part of a controlled research project approved by an accredited institution of higher education or under the supervision of a government agency;

(3) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

(c) The department may not grant a waiver under this section unless the pharmacist or practitioner first agrees in writing that, if the waiver is granted, the pharmacist or practitioner will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board on at least a daily basis using a form approved by the board.

(d) A request for a waiver under this section must be in writing using an application form provided by the board and sent to the board.

(e) The department's grant or denial of a waiver request constitutes a final agency action unless, no later than 30 days after the department issues notice of the grant or denial, the pharmacist or practitioner files a written notice of appeal with the board.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) A pharmacist or practitioner must inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.875. SOLICITED REQUESTS FOR INFORMATION FROM NON-REGISTERED PERSONS. (a) A patient authorized under AS 17.30.200(d)(6) to receive information from the controlled substance prescription database, the patient's authorized agent, or in the case of a unemancipated minor unable to give consent for medical services under AS 25.20.025(a), the minor's parent or legal guardian, may request profile information from the controlled substance prescription database concerning the patient if the person requesting the information

(1) submits the request on a form provided by the board;

(2) pays a $10 fee; and

(3) does one of the following:

(A) if a patient, presents to the department, in person, government-issued photographic identification confirming the patient's identity as the same person on whom profile information is sought;

(B) if a patient, submits a signed and notarized request

(i) verifying that the patient is the same person on whom profile information is sought; and

(ii) providing the patient's full name, address, and date of birth;

(C) presents a valid power of attorney concerning the patient, or presents

(i) verification that the person requesting the information is the parent, legal guardian, or legal administrator of a minor, incapacitated person, or deceased person on whom profile information is sought; and

(ii) if the person is a parent or legal guardian of a patient who is a minor, verification that the patient is not an emancipated minor legally able to consent to medical treatment under AS 25.20.025.

(b) Profile information may be

(1) disseminated in person; or

(2) mailed certified mail, return receipt requested, no later than five days after the date that the department receives a request that meets the requirements of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.880. REPORTS. (a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.875. The register includes the following information:

(1) the date on which the request was received;

(2) the name of the patient and the patient's date of birth;

(3) the name, title, and address of the individual requesting the profile;

(4) the date on which the information was disseminated, mailed, or sent by facsimile transmission.

(b) The register and the information in it are confidential and may only be accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52.855 - 12 AAC 52.890.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.885. PURGED DATABASE RECORDS. The following information will be purged from the PDMP database after two years have elapsed from the date the prescription was dispensed:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890. GROUNDS FOR DISCIPLINE. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a pharmacist is grounds for the imposition of disciplinary sanctions under AS 08.01.075 and AS 08.80.261. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a practitioner not licensed by this board shall be reported to the practitioner’s licensing board.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.895. CORRECTING INFORMATION IN DATABASE. (a) To request a correction under AS 17.30.200(k)(2) to information in the controlled substance prescription database concerning a person, that person must submit to the board

(1) on a form or in a format prescribed by the board,

(A) a description of the information asserted to be incorrect, and the correction requested;

(B) the mailing and physical address and telephone number of the requester; and

(C) a signed, sworn statement attesting to the truth of the corrected information;

(2) documentation to support the correction requested; and

(3) proof of the requester's identity.

(b) If the board determines that it

(1) has sufficient information to make a determination, the board will

(A) notify the requester that the request is granted; or

(B) issue a written denial of the request, if the board determines that the information for which a correction was requested is accurate and complete; in the denial, the board will notify the requester that the requester may request, in accordance with (c) of this section, an administrative hearing to contest the denial;

(2) lacks sufficient information to grant or deny the request, the board

(A) will request additional information from the requester; and

(B) will not act on the request until after the additional information is received.

(c) If the board receives, no later than 30 days after it issues a denial under (b)(1)(B) of this section, a written request for an administrative hearing, the board will conduct an administrative hearing of the denial through the Office of Administrative Hearings in accordance with AS 44.62 (Administrative Procedure Act) and AS 44.64. If the board does not receive a request, the denial is a final administrative decision for purposes of judicial review.

Authority: AS 08.80.005 AS 08.80.050 AS 17.30.020
AS 08.80.030

ARTICLE 10.
DISCIPLINARY GUIDELINES.

Section

12 AAC 52.900. PURPOSE OF DISCIPLINARY GUIDELINES. The disciplinary guidelines in 12 AAC 52.900 - 12 AAC 52.980 are established to ensure the board's disciplinary policies are known and are administered consistently and fairly.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.910. VIOLATIONS. (a) A person who is licensed under AS 08.80 and this chapter who, after a hearing under AS 44.62 (Administrative Procedure Act), is found to have violated a provision of AS 08.80 or this chapter is subject to the disciplinary penalties listed in AS 08.01.075, including public notice of the violation and penalty in appropriate publications.

(b) Nothing in the guidelines set out in 12 AAC 52.920 prohibits the board from imposing greater or lesser penalties than those described in 12 AAC 52.920 or restricting the practice of a licensee depending upon the circumstances of a particular case.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.920. DISCIPLINARY GUIDELINES. (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(7) refusing entry into a pharmacy for an inspection authorized by AS 08.80 or this chapter;
(8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;
(9) operating a pharmacy in an unsanitary manner;
(10) making a false or fraudulent claim concerning a drug;
(11) refilling a prescription drug order for a period of time in excess of one year from the date of issue of that prescription drug order;
(12) violating the provisions of a board order or memorandum of agreement;
(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;
(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:
(A) a pharmacist-in-charge of a pharmacy;
(B) a sole proprietor or individual owner of a pharmacy;
(C) a partner in the ownership of a pharmacy; or
(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy;
(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;
(16) knowingly delegating a function, task, or responsibility that is part of the practice of pharmacy to a person who is not licensed to perform that function, task, or responsibility when the delegation is contrary to AS 08.80 or this chapter or the delegation involves a substantial harm or risk to a patient;
(17) failing to exercise adequate supervision over a person who is authorized to practice only under the supervision of a pharmacist;
(18) violating AS 08.80.315 dealing with the confidentiality of records;
(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, or sex in the provision of a service that is part of the practice of pharmacy;
(20) offering, giving, soliciting, or receiving compensation for referral of a patient;
(21) violating AS 08.80.261(a)(3); or
(22) violating AS 17.30.200 or a regulation adopted under AS 08.80.030 or AS 17.30.200 dealing with the PDMP.

(b) The board will, in its discretion, revoke a license if the licensee
(1) commits a violation that is a second offense;
(2) violates the terms of probation from a previous offense;
(3) violates AS 08.80.261(a)(1) or (4);
(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;
(5) is professionally incompetent if the incompetence results in risk of injury to a patient.

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee
(1) wilfully or repeatedly violates AS 08.80 or this chapter; or
(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

(d) The board will review, on an individual basis, the need for revocation or limitation of a license of a licensee who practices or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy.

Authority: AS 08.01.075 AS 08.80.005 AS 08.80.030 AS 08.80.261 AS 08.80.315 AS 08.80.460 AS 17.30.200

12 AAC 52.925. GROUNDS FOR DENIAL OR DISCIPLINE FOR CRIMINAL HISTORY. (a) As used in AS 08.80.261 and this chapter, crimes that affect the applicant's or licensee's ability to practice competently and safely include
(1) murder;
(2) manslaughter;
(3) criminally negligent homicide;
(4) assault;
(5) sexual assault;
(6) sexual abuse of a minor;
(7) unlawful exploitation of a minor, including possession or distribution of child pornography;
(8) incest;
(9) indecent exposure;
(10) robbery;
(11) extortion;
(12) stalking;

(13) kidnapping;
(14) theft;
(15) burglary;
(16) forgery;
(17) endangering the welfare of a child;
(18) endangering the welfare of a vulnerable adult;
(19) unlawful distribution or possession for distribution of a controlled substance; for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;
(20) reckless endangerment.

(b) Convictions of an offense in another jurisdiction with elements similar to an offense listed in (a) of this section affect the applicant's or licensee's ability to practice competently and safely.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261

12 AAC 52.930. TERMS OF PROBATION. The board will, in its, discretion, subject a licensee who is placed on probation to one or more of the following terms of probation, and to other relevant terms of probation, including those in 12 AAC 52.940 - 12 AAC 52.960:

(1) obey all laws pertaining to the practice of pharmacy in this state;
(2) fully comply with the probation program established by the board and cooperate with representatives of the board;
(3) notify the board in writing of the dates of departure and return if the licensee leaves the state to reside or practice pharmacy outside the state;
(4) report in person at meetings of the board or to its designated representatives during the period of probation, as directed by the board;
(5) submit written reports and verification of actions as required by the board during the period of probation;
(6) if employed in the practice of pharmacy at any time during the period of probation, have the employer submit to the board verification that the employer understands the conditions of probation;
(7) be employed as a pharmacist only in a setting in which full supervision is provided and not personally act as a supervisor.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.940. USE OF ALCOHOL OR CONTROLLED SUBSTANCES. (a) In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for the habitual abuse of alcohol or illegal use of controlled substances may also be subject to one or more of the following:

(1) physical and mental health examinations as determined by the board to evaluate the licensee's ability to perform the professional duties of a pharmacist;
(2) as determined by the board, participation until completion in an ongoing program of rehabilitative counseling, Alcoholics Anonymous, Narcotics Anonymous, or an impaired practitioner group that includes progress reports from the care provider when requested by the board;
(3) abstaining from the personal use of alcohol or controlled substances in any form except when lawfully prescribed by a practitioner licensed to practice in Alaska;
(4) submitting to tests and samples required for the detection of alcohol or controlled substances at the request of the board or the board's representative.

(b) Access to a controlled substance in the work setting will, in the board's discretion, be restricted.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.950. PROBATION TERMS FOR PROFESSIONAL INCOMPETENCE. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation after being found professionally incompetent may be subject to one or more of the following terms of probation:

(1) successful completion of an appropriate course or courses in pharmacy, as determined by the board, before the end of the probationary period; or
(2) participation in 15 contact hours of appropriate continuing education in pharmacy.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.960. MENTAL OR PHYSICAL DISABILITIES. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for practicing or attempting to practice pharmacy while afflicted with a physical or mental illness, deterioration, or disability that interferes with the licensee's performance of pharmacy may be subject to a physical or mental health examination to evaluate the

licensee's ability to perform the professional duties of a pharmacist and if medically determined to be necessary, may be required to participate in and complete a recommended treatment program that includes written progress reports from the care provider when requested by the board.

Authority: AS 08.01.075 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.970. REINSTATEMENT OF A SUSPENDED LICENSE. The board may reinstate a suspended license only if the requirements of the suspension order have been met.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.980. REINSTATEMENT OF A REVOKED LICENSE. (a) One year after revocation of a license, a licensee may apply to the board in writing for reinstatement of the license.

(b) The applicant for reinstatement shall appear before the board.

(c) The board will, in its discretion, impose restrictions upon the pharmacist or pharmacy when reinstating a license.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

ARTICLE 11.
GENERAL PROVISIONS.

Section

12 AAC 52.985. EMERGENCY PREPAREDNESS. (a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor that results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

(b) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor of another state or territory, or a province of Canada which results in an individual being temporarily relocated to Alaska who is unable to refill an existing prescription, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

(c) Repealed 4/3/2020.

(d) Repealed 4/3/2020.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110.

(f) During a disaster emergency declared by the governor of this state,

(1) a pharmacist or pharmacist intern may administer immunizations, in accordance with 12 AAC 52.992, without obtaining or maintaining a CPR certificate;

(2) the notice required under 12 AAC 52.150(a) need not be provided until 30 days after the date that the disaster emergency ends;

(3) an application under 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.120, 12 AAC 52.423, 12 AAC 52.610, 12 AAC 52.696, and 12 AAC 52.697 does not need to be notarized.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.990. DISPLAY OF LICENSE CERTIFICATE. A licensee shall conspicuously display, in the practice site, the licensee's current license certificate. Pending receipt of the current license certificate from the department, the licensee shall display the department's Internet web site posting confirming licensure. The current license certificate, or web site posting confirming licensure, of a licensee practicing in an institutional facility may be displayed in a central location.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: The current posting confirming licensure can be found at the Internet web site of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing: www.commerce.state.ak.us/occ/search3.htm.

12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT. (a) A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant's or licensee's ability to practice competently and safely, issued against the licensee not later than 30 days after the date of the disciplinary decision or conviction.

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.315
AS 08.80.005 AS 08.80.261 AS 08.80.460

12 AAC 52.992. INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS. (a) Before a pharmacist may independently administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist

(1) must successfully complete a course accredited by the Accreditation Council for Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

(A) basic immunology, vaccine, and immunization protection;
(B) diseases that may be prevented by vaccination or immunization;
(C) current CDC immunization schedules;
(D) vaccine storage and management;
(E) informed consent;
(F) physiology and techniques for administration of immunizations;
(G) pre-immunization and post-immunization assessment and counseling;
(H) immunization reporting and records management; and
(I) identifying, responding to, documenting, and reporting adverse responses;

(2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training;

(3) who has not administered a vaccine during the past 10 years must complete a course as described in (1) of this subsection before administering a vaccine; and

(4) must adhere to 12 AAC 52.320, including continuing education requirements under 12 AAC 52.320(e).

(b) A pharmacy from which a pharmacist administers a human vaccine or related emergency medication under this section

(1) must stock the following emergency medications in an emergency medication kit that is separate from the regular dispensing inventory, and that is carried by the pharmacist if providing off-site immunizations:

(A) oral and injectable diphenhydramine; and
(B) adult and pediatric auto-inject epinephrine devices, or injectable epinephrine;

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed; the manual must

(A) designate either the pharmacist-in-charge or an assigned vaccine coordinator who will be responsible for maintaining the policy and procedures manual;
(B) document that the policy and procedures manual has been reviewed and updated annually;
(C) address how vaccine related adverse reactions are to be reported to the CDC's and FDA's Vaccine Adverse Event Reporting System (VAERS);
(D) address proper vaccine storage, handling, and maintenance, including maintaining manufacturer-recommended temperatures during transportation of vaccines;
(E) address proper disposal of used or contaminated supplies;
(F) contain a written emergency protocol for handling accidental needlesticks and adverse reactions, including the administration of related emergency medications; and
(G) detail how records must be kept;

(3) must have access to the latest edition of the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* as a reference; and

(4) must display each pharmacist's certification of completing the immunization course described in (a)(1) of this section.

(c) Before administering an immunization or related emergency medication, a pharmacy intern must

(1) have completed an ACPE-accredited immunization course or other comparable course that meets the requirements of (a)(1) of this section;

(2) maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training; and

(3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

(d) A pharmacist or pharmacist intern administering a vaccine must offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A pharmacist or intern independently administering a vaccine must comply with 7 AAC 27.650.

(f) For purposes of this section, a pharmacist independently administers a human vaccine or related emergency medication if

(1) the pharmacist meets the requirements of this chapter and is the prescriber and administrator of the vaccine; or

(2) a pharmacist intern meeting the requirements of this chapter administers the vaccine, and the pharmacist supervising the pharmacist intern is the prescriber.

(g) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075.

(h) In this section,

(1) "CDC" means the United States Department of Health and Human Services, Centers for Disease Control and Prevention;

(2) "FDA" means the United States Food and Drug Administration.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.168 AS 08.80.261 AS 08.80.480

12 AAC 52.993. EXECUTIVE ADMINISTRATOR. The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance must be reviewed by a board member;

(2) attend state or national meetings or conferences on behalf of the board;

(3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;

(4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;

(5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

12 AAC 52.994. INDEPENDENT DISPENSING OF OPIOID OVERDOSE DRUGS BY PHARMACISTS. (a) A pharmacist may independently dispense an opioid overdose drug approved for use as an opioid overdose drug by the United States Food and Drug Administration. Before a pharmacist independently dispenses an opioid overdose drug to a recipient, the pharmacist shall

(1) in accordance with 12 AAC 52.340, complete a single training session that consists of one hour of continuing education specific to the use of an opioid overdose drug;

(2) question the recipient to determine if there are any known contraindications to opioid overdose drug usage for the potential user; and

(3) provide the recipient information about opioid overdose prevention, recognition, and response to opioid overdose drugs.

(b) A pharmacist may

(1) supply an opioid overdose drug as

(A) an intramuscular injection;

(B) an intranasal spray;

(C) an auto-injector; or

(D) any other product forms approved by the United States Food and Drug Administration; and

(2) recommend other optional items when appropriate, including

(A) alcohol pads;

(B) rescue breathing masks; or

(C) rubber gloves.

(c) When dispensing an opioid overdose drug

(1) the pharmacist shall

(A) label the drug in accordance with 12 AAC 52.480;

(B) ensure that the label includes appropriate directions; the label may not consist of the sole direction "use as directed";

(C) ensure that the label includes directions to call 911 or other available emergency services; and

(D) document the drug as a prescription in the medication record of the recipient in accordance with 12 AAC 52.450;

(2) the pharmacist may

(A) in accordance with 12 AAC 52.585, provide the recipient with counseling and information on the drug furnished, including

(i) dosing;

(ii) administration;

(iii) effectiveness;

(iv) adverse effects;

(v) storage conditions;

(vi) shelf life; and

(vii) safety;

(B) offer the recipient information or referrals to appropriate resources including information about addiction treatment, recovery services, or medication disposal resources, if the recipient indicates interest in that information.

(d) Nothing in this section restricts the ability of a pharmacist to furnish an opioid overdose drug by means of an authorized practitioner prescription under 12 AAC 52.460 or 12 AAC 52.490.

(e) In this section,

(1) "opioid overdose drug"

(A) has the meaning given in AS 08.80.168;

(B) includes naloxone hydrochloride;

(2) "recipient" means the person to whom an opioid overdose drug is furnished.

Authority: AS 08.80.030 AS 08.80.168 AS 08.80.480

12 AAC 52.995. DEFINITIONS. (a) In this chapter, unless the context requires otherwise,

(1) "ACPE" means Accreditation Council for Pharmacy Education;

(2) "approved program" means a continuing education activity that is a live program, home study, or other mediated instruction delivered by an approved or accredited provider;

(3) "approved provider" means an individual, institution, organization, association, corporation, or agency offering an approved program under 12 AAC 52.340 and is not an accredited provider;

(4) "authorized inspector" means a member of the board or an investigator with the division assigned occupational licensing functions in the department;

(5) "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(6) "blood component" means that part of blood separated by physical or mechanical means;

(7) "board" means the Alaska Board of Pharmacy;

(8) "care provider" means a person or organization that by the nature of experience and training is qualified, in the opinion of the board, to provide substance abuse counseling, rehabilitation, or related services to the public through established and recognized treatment programs;

(9) "consultant pharmacist" means a licensed pharmacist retained by written agreement with an institutional facility to consult on a routine basis with an institutional facility about the practice of pharmacy as it relates to that facility;

(10) "contact hour" means a unit of measure of educational credit that is equivalent to approximately 50 minutes of participation in an organized learning experience; a continuing education unit or "CEU" is equivalent to ten contact hours;

(11) "DEA" means the United States Drug Enforcement Administration;

(12) "department" means the Department of Commerce, Community, and Economic Development;

(13) "direct supervision" means supervision that insures adequate safety controls either by personal supervision or through a telepharmacy system;

(14) "home study" and "other mediated instruction" mean continuing education activities that are not conducted as live programs, including audio tapes, video tapes, television, computer assisted instruction, journal articles, or monographs;

(15) "institutional facility" means a

(A) hospital;

(B) long-term care facility, including a nursing home, convalescent home, or other related facility;

(C) mental health facility;

(D) rehabilitation center;

(E) psychiatric center;

(F) developmental disability center;

(G) drug abuse treatment center;

(H) family planning clinic;

(I) penal institution;

(J) hospice; or

(K) public health facility;

(16) "institutional pharmacy" means a pharmacy located in an institutional facility;

(17) "licensee" means a person who is licensed under AS 08.80 and this chapter;

(18) “live program” means an on-site continuing education activity, including a lecture, symposium, live teleconference, or workshop;

(19) “sterile pharmaceutical” means a drug dosage form free from living microorganisms (aseptic);

(20) “wholesale distribution” means distribution of prescription drugs to a person other than a consumer or patient, but does not include an activity described in 12 AAC 52.695;

(21) “central pharmacy” means a pharmacy providing remote pharmacy services through a telepharmacy system;

(22) “personal supervision” means supervision that includes visual or physical proximity to ensure adequate safety controls;

(23) “pharmacy” includes a central pharmacy and a remote pharmacy;

(24) “remote pharmacy” means a facility that provides pharmacy services, including the storage and distribution of prescription drugs, drug regimen review, and patient counseling through a telepharmacy system;

(25) “still image capture” means a specific image captured electronically from a video or other image capture device;

(26) “store and forward” means a video or still image record that is saved electronically for future review;

(27) “telepharmacy system” means a system under the direct supervision of a licensed pharmacist that monitors the dispensing and distribution of prescription drugs and provides for related drug use review and patient counseling services through a computer link and a video link with sound;

(28) “accredited provider” means an individual, institution, organization, association, corporation, or agency that is recognized by the ACPE as able to provide quality continuing education programs;

(29) “filling pharmacist” means a pharmacist participating in shared pharmacy services that processes or fills a prescription order for a patient;

(30) “filling pharmacy” means a pharmacy participating in shared pharmacy services that processes or fills a prescription order for a patient;

(31) “requesting pharmacist” means a pharmacist participating in shared pharmacy services that forwards a prescription order to another participating pharmacy or pharmacist to be processed or filled;

(32) “requesting pharmacy” means a pharmacy participating in shared pharmacy services that forwards a prescription order to another participating pharmacy to be processed or filled;

(33) “shared pharmacy services” means a system allowing the processing by a participating pharmacist or a pharmacy of a request from another participating pharmacist or pharmacy to enter or review a prescription drug order or process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

(34) “dispenser” means a practitioner who delivers a controlled substance to an ultimate user or research subject under the lawful order of a practitioner; in this paragraph, "delivers" includes the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery;

(35) “profile” means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance;

(36) “PDMP” means the prescription drug monitoring program’s controlled substance prescription database;

(37) “moral turpitude” includes conduct that is considered contrary to community standards of justice, honesty, or good morals;

(38) “pharmacy technician who holds a national certification” means a pharmacy technician, licensed by the board, who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA).

(b) In AS 08.80.315(3), “other persons or governmental agencies” include investigators for the department who are assigned to conduct investigations under AS 08.

(c) In AS 08.80.030(b)(7), “monitoring of drug therapy” means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. “Monitoring of drug therapy” includes

(1) collecting and reviewing records of patient drug use histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under 12 AAC 52.240.

(d) In AS 17.30.200 and 12 AAC 52.855 – 12 AAC 52.895, “practitioner” has the meaning given in AS 11.71.900.

(e) In 12 AAC 52.610 – 12 AAC 52.697, “facility manager” means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.159 AS 11.71.900 AS 17.30.200 AS 17.30.900

CHAPTER 30.
CONTROLLED SUBSTANCES

Sec. 17.30.200. Controlled substance prescription database. (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (t) of this section.

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule II, III, or IV controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law other than those dispensed or administered under the circumstances described in (t) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

(3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and

(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:

(1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;

(2) authorized board personnel or contractors as required for operational and review purposes;

(3) a licensed practitioner having authority to prescribe controlled substances or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(4) a licensed or registered pharmacist having authority to dispense controlled substances or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable cause for the access and use of the information;

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;

(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;

(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs provided to recipients of medical assistance;

(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber; and

(11) a practitioner, pharmacist, or clinical staff employed by an Alaska tribal health organization, including commissioned corps officers of the United States Public Health Service employed under a memorandum of agreement; in this paragraph, "Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

(A) a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this sub-subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;

(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(v) in a hospice or nursing home that has an in-house pharmacy; or

(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.

(*l*) A person

(1) with authority to access the database under (d) of this section who knowingly

(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;

(B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;

(C) allows another person who is not authorized to access the database to access the database commits a class C felony;

(2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.

(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures

(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to

(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;

(B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;

(C) increase coordination among prescription drug monitoring program partners;

(D) involve stakeholders in the planning process;

(2) shall include information related to the

(A) security of the database; and

(B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.

(n) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.

(o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (n) of this section.

(p) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section

(1) must be provided to the practitioner;

(2) is confidential;

(3) may not disclose information that is confidential under this section;

(4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.

(q) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.

(r) The Department of Commerce, Community, and Economic Development shall

(1) assist the board and provide necessary staff and equipment to implement this section; and

(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (n) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall

(A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and

(B) consult with the board to establish the fees under this paragraph.

(s) Notwithstanding (p) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if a controlled substance is

(1) administered to a patient at

(A) a health care facility; or

(B) a correctional facility;

(2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital

(A) inpatient pharmacy; or

(B) emergency department.

(u) In this section,

(1) "board" means the Board of Pharmacy;

(2) "database" means the controlled substance prescription database established in this section;

(3) "knowingly" has the meaning given in AS 11.81.900;

(4) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160;

(5) "pharmacist-in-charge" has the meaning given in AS 08.80.480.

General Requirements.

(a) Each pharmacy is of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and/or preparation of prescription drug orders.

(b) There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(c) The prescription department and all areas where drugs are stored are well lighted, well ventilated, dry, and maintained in a clean and orderly condition. Walls, floors, ceilings, and windows are clean and in general good repair and order.

(d) Each pharmacy has a sink with hot and cold running water within the pharmacy and maintained in a sanitary condition.

(e) There are refrigeration facilities with a thermometer in the prescription department for the proper storage of drugs requiring refrigeration. Temperatures in the refrigerator are maintained within United States Pharmacopeia standards.

(f) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.

Equipment and Supplies.

(a) All pharmacies have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(b) All equipment is kept in a clean and orderly manner. Equipment used in the compounding or preparation of prescription drug orders (counting, weighing, measuring, mixing, stirring, and molding equipment) is clean and in good repair.

Library. A reference library is maintained which includes the following:

(1) A current copy (hard-copy or electronic media access) of the Alaska Pharmacy Statutes and Regulations.

(2) At least one current or updated reference (hard-copy or electronic media access) from each of the following categories:

(A) Patient information – examples are;

(i) USP Dispensing Information; or

(ii) Patient Drug Facts; or

(iii) reference text or information leaflets which provide patient information.

(B) General information – examples are;

(i) Facts and Comparisons; or

(ii) USP Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or

(iii) Remington's Pharmaceutical Sciences.

(C) Clinical Information – examples are;

(i) AHFS Drug Information; or

(ii) Micromedex; or

(iii) Clinical Pharmacology; or

(iv) reference material pertinent to the practice setting.

(3) The telephone number of the nearest poison control center is readily available.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines on facilities, reference materials, equipment, supplies and other matters. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.400.

STERILE PHARMACEUTICALS
February 2008

Scope and Purpose.

The purpose of this pamphlet is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (eg. home, hospital, extended care facility, hospice, practitioner's office).

Definitions.

(a) "Biological Safety Cabinet" – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(b) "Class 100 Environment" – an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209D.

(c) "Cytotoxic" – a pharmaceutical that has the capability of killing living cells.

(d) "Parenteral" – a sterile preparation of drugs for injection through one or more layers of the skin.

(e) "Sterile Pharmaceutical" – dosage form free from living micro-organisms (aseptic).

Policy and Procedure Manual.

(a) A policy and procedure manual is prepared and maintained for the compounding, dispensing, and delivery of sterile pharmaceutical drug orders. The manual is reviewed and revised as necessary on an annual basis by the pharmacist-in-charge and is available for inspection at the pharmacy.

(b) The manual includes policies and procedures, as applicable, for:

(1) Clinical services;
(2) Sterile product handling, preparation, dating, storage and disposal;
(3) Major and minor spills of cytotoxic agents;
(4) Disposal of unused supplies and medications;
(5) Drug destruction and returns;
(6) Drug dispensing;
(7) Drug labeling;
(8) Duties and qualifications for professional and nonprofessional staff;
(9) Equipment use and maintenance;
(10) Handling of infectious waste pertaining to drug administration;
(11) Infusion devices and drug delivery systems;
(12) Training and orientation of professional and non-professional staff commensurate with the services provided;
(13) Dispensing of investigational medications;
(14) Quality control and quality assurance;
(15) Recall procedures;
(16) Infection control;
(17) Suspected contamination of sterile products;
(18) Orientation of employees to sterile technique;
(19) Sanitation;
(20) Security; and
(21) Transportation.

Physical Requirements.

(a) The pharmacy designates an area for the preparation of sterile products that is functionally separate from areas for the preparation of non-sterile products and is constructed to minimize traffic and airflow disturbances. It is used only for the preparation of these specialty products. It is of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy preparing parenteral products has:

(1) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environments during normal activity;

(2) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biological safety cabinets;

(3) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand washing prior to compounding;

(4) The designated area shall have hard cleanable surfaces, walls, floors and ceilings;

(5) Appropriate disposal containers for used needles, syringes, etc. and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patient's homes;

(6) Refrigerator/freezer with thermometer;

(7) Temperature controlled delivery container, if appropriate;

(8) Infusion devises, if appropriate;

(9) Supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(c) Laminar flow hood certification (or clean room certification, if applicable) are conducted at least every six months by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports are maintained for at least two years. In addition, prefilters are replaced on a regular basis and the replacement date documented.

(d) The pharmacy has current reference materials related to sterile products. These reference materials will contain information on stability, incompatibilities, preparation guidelines, and the handling of chemotherapy drug products.

Personnel.

(a) All personnel participating in the preparation and/or dispensing of compounded sterile pharmaceuticals are trained in this specialized function, including the principles of aseptic technique. All duties and responsibilities of personnel are consistent with their training and experience.

(b) Pharmacies providing parenteral products to non-hospitalized patients have a pharmacist accessible twenty-four hours per day to respond to patient's and other health professional's questions and needs.

Drug Distribution and Control.

(a) In addition to labeling required for all dispensed prescription drug orders, the labeled container of a sterile pharmaceutical bears the expiration date of the preparation based upon published data.

(b) Delivery Service. The pharmacist-in-charge assures the environmental control of all products shipped. Therefore, any compounded sterile pharmaceutical is shipped or delivered to a patient in appropriate temperature controlled (as defined by United States Pharmacopeia Standards) delivery containers and stored appropriately in the patient's home or outpatient location.

(c) Disposal of Infectious/Hazardous Waste. The pharmacist-in-charge is responsible for assuring there is a system for the disposal of cytotoxic waste and infectious waste in a manner so as not to endanger the public health.

(d) Emergency Kit. When sterile pharmaceuticals are provided to home care patients, the pharmacy may supply the licensed nurse with emergency drugs, if the prescribing practitioner has authorized the use of these drugs by a protocol for use in an emergency situation (e.g. anaphylactic shock).

Cytotoxic Drugs.

The following additional requirements are necessary for those pharmacies that prepare cytotoxic drugs to assure the protection of the personnel involved:

(a) All cytotoxic drugs are compounded within a vertical flow, Class II, Biological Safety Cabinet. Policy and procedures are developed for the cleaning of the laminar airflow hood between compounding cytotoxic drugs and other parenteral products, if applicable.

(b) Protective apparel is worn by personnel compounding cytotoxic drugs. This includes disposable gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs are used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents are developed and included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Patient Training.

If appropriate, the Pharmacist demonstrates or documents the patient's training and competency in managing the type of therapy provided by the Pharmacist to the patient in the home environment. A pharmacist is involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The Pharmacist is responsible for seeing the patient's competency in the above areas is reassessed on an ongoing basis.

Quality Control and Quality Assurance Procedures.

(a) Quality Control. There is a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities. Procedures are in place to assure the pharmacy is capable of consistently preparing pharmaceuticals which are sterile and stable. Quality control procedures include, but are not limited to, the following:

(1) recall procedures;

(2) storage and dating;

(3) documentation of appropriate functioning of refrigerator, freezer, and other equipment;

(4) documentation of aseptic environmental control device certification and the regular replacement of prefilters;

(5) a process to evaluate and confirm the quality of the prepared pharmaceutical product; and

(6) if bulk compounding of parenteral solutions is performed utilizing non-sterile chemicals, extensive end product testing is documented prior to the release of the product from quarantine. This process includes appropriate tests for particulate matter and pyrogens.

(b) Quality Assurance.

(1) There is a documented, ongoing quality assurance program for monitoring and evaluating personnel performance and patient outcomes to assure efficient drug delivery, patient safety, and positive patient outcomes.

(2) There is documentation of quality assurance audits at regular, planned intervals which may include infection control, sterile technique, delivery systems/times, order transcription accuracy, drug administration systems, adverse drug reactions, and drug therapy appropriateness.

(3) A plan for corrective action of problems identified by quality assurance audits is developed which includes procedures for the documentation of identified problems and action taken.

(4) A periodic evaluation of the effectiveness of the quality assurance activities is completed and documented.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.430.

(a) A pharmacist may compound drugs in limited quantities before receiving a valid prescription drug order if the pharmacist has a historical basis of valid prescription drug orders generated solely within an established relationship between the pharmacist, a patient, and a prescribing practitioner for the amount of drugs compounded. Compounding drugs in an amount above that for which there is a historical basis is considered manufacturing.

(b) Compounding includes the preparation

(1) according to a prescription drug order of drugs or devices that are not commercially available;

(2) of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist.

(c) When a compounded product is to be substituted for a commercially available product, both the patient and the prescribing practitioner must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription drug order or in the computerized patient medication record. The prescribing practitioner's authorization is in addition to signing to permit substitution on a prescription drug order or advising verbally that substitution is permitted. The reconstitution of commercially available products according to the manufacturer's guidelines is permissible without notice to the prescribing practitioner.

(d) A pharmacist may not offer compounded drug products to prescribing practitioners, pharmacists, or pharmacies for resale except in the course of professional practice for a prescribing practitioner to administer to an individual patient. The distribution of inordinate amounts of compounded products without a relationship between the pharmacist and the prescribing practitioner and patient is considered manufacturing.

(e) A pharmacist may receive, store, and use drug substances for compounding prescriptions that meet official compendia requirements. A pharmacist shall use the pharmacist's professional judgment to receive, store, and use drug substances for compounding prescriptions not found in official compendia.

PERSONNEL

A pharmacist engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.

COMPOUNDING FACILITIES

(a) A pharmacy engaging in compounding shall have a specifically designated and adequate area for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation must be provided in all drug compounding areas. Potable water must be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area of the pharmacy must be provided. The facilities must include hot and cold water, soap or detergent, and air-driers or single use towels.

(d) The area used for the compounding of drugs must be maintained in a clean and sanitary condition. It must be free of infestation by insects, rodents, and other vermin. Trash must be held and disposed of in a timely and sanitary manner. Sewage and other refuse must be disposed of in a safe and sanitary manner.

(e) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous

cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be used in order to prevent cross-contamination.

RECORDS AND REPORTS

(a) A pharmacist shall keep records of all compounded products for two years. The records must be readily available for authorized inspection at the pharmacy.

(b) A pharmacist shall ensure that there are formulas maintained electronically or manually. A formula must include ingredients, amounts, methodology and equipment, if needed, and special information regarding sterile compounding.

(c) A pharmacy engaging in compounding must have written procedures for the compounding of drugs to assure that the finished products have the identity, strength, quality, and purity they are represented to possess. The procedures must include a listing of the components, their amounts in weight or volume, the order of component mixing, and a description of the compounding process. The procedures must list all equipment and utensils and the container or closure system relevant to the sterility and stability of the intended use of the drug. The procedures must be followed in the execution of the drug compounding procedure.

(d) A pharmacist shall accurately weigh, measure, or subdivide as appropriate the components for drug product compounding. The compounding pharmacist shall check these operations at each stage of the compounding process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another container, the new container must be identified with the component name and the weight or measure.

(e) To assure the reasonable uniformity and integrity of compounded drug products, written procedures must be established and followed that describe the tests or examinations to be conducted on the product compounded. The control procedures must be established to monitor the output and to validate the performance of those compounding processes that include the following when appropriate:

(1) capsule weight variation;

(2) adequacy of mixing to assure uniformity and homogeneity;

(3) clarity, completeness, or pH of solutions;

(f) A pharmacy engaging in compounding shall establish and follow appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile. The procedures must include validation of any sterilization process.

(g) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include

(1) the date of preparation;

(2) the lot numbers – the lot numbers may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If a lot number is assigned by the pharmacy, the pharmacy shall record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components;

(3) the expiration date of the finished product. This date may not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber or to be stored in until dispensing. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist;

(4) the signature or initials of the pharmacist performing the compounding;

(5) initials of the person preparing each process;

(6) initials of the pharmacist supervising each process;

(7) a formula for the compounded product maintained in a readily retrievable form;

(8) the name of the manufacturer of the raw materials;

(9) the quantity in units of finished products or grams of raw materials; and

(10) the package size and the number of units prepared.

(h) "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in the product.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist on compounding practices. Professional conduct by a licensee includes adherence to these guidelines.
See 12 AAC 52.440.

Board or Commission: Alaska Board of Pharmacy

Meeting Date: _____

Agenda Item # _____ Tab #_____ Topic: _____

Primary Motion

Motion:

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

Subsidiary Motion or Amendment

Motion:

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

EXECUTIVE SESSION MOTION

Sec. 44.62.310. Government meetings public.
(c) The following subject may be considered in an executive session:

(1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;
(2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;
(3) matters which by law, municipal charter, or ordinance are required to be confidential;
(4) matters involving consideration of government records that by law are not subject to public disclosure.

MOTION WORDING:

"In accordance with the provisions of Alaska Statute 44.62.310 (c), I move to go into executive session for the purpose of discussing (select the appropriate statutory citation for the situation):

(1) **matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;** ***OR***

(2) **subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;** ***OR***

(3) **matters which by law, municipal charter, or ordinance are required to be confidential;** ***OR***

(4) **matters involving consideration of government records that by law are not subject to public disclosure.**

Board staff is requested to remain during the session ***OR***
Board only to remain during session."

Staff will then state **"The board is off the record at _____(time)."**

ORDER OF OPERATIONS TO ACT AS A BOARD

1. A member seeks recognition from the chair.
2. The member is recognized by the chair and "has the floor."
3. The member makes a motion.
4. The motion is seconded (if appropriate, see chart on other side).
5. The chair (or staff, if delegated) restates the motion to the body.
6. Board or commission debates the motion.
7. Subsidiary motions are made, if any: Amend, table, send to committee (see chart on other side).
8. Board or commission votes on subsidiary motion, if any.
9. Board or commission votes on the main motion either by roll call or unanimous consent.
10. The chair (or staff) announces the result of the vote.

Best practices:

1. Makers of motions should write them down before verbalizing, then hand the written motion to the secretary once the motion has been made on the floor.
2. It is appropriate for the chair to call for a brief break ("at ease") to untangle the motions when operations become confused. Do not proceed in confusion.

PURPOSE	YOU SAY	INTER-RUPT?	2ND?	DEBATE?	AMEND?	VOTE?
Bring business before the board	I move to…	No	Yes	Yes	Yes	Majority
Modify wording of motion	I move to amend the motion by…	No	Yes	Yes	Yes	Majority
Lay aside temporarily	I move to lay the question on the table.	No	Yes	No	No	Majority
Close debate	I move the previous question.	No	Yes	No	No	2/3
Limit or extend debate	I move that debate be limited to…	No	Yes	No	Yes	2/3
Postpone to a certain time	I move to postpone the motion to…	No	Yes	Yes	Yes	Majority
Refer to committee	I move to refer the motion to…	No	Yes	Yes	Yes	Majority
Kill main motion	I move that the motion be postponed indefinitely.	No	Yes	Yes	Yes	Majority
Make follow agenda	I call for the orders of the day.	Yes	No	No	No	None or 2/3 to overrule
Take matter from table	I move to take from the table…	No	Yes	No	No	Majority
Cancel previous action	I move to rescind…	No	Yes	Yes	Yes	2/3 w/o prior notice
Reconsider motion	I move to reconsider…	No	Yes	Varies	No	Majority
Take a break	I move to recess for…	No	Yes	No	Yes	Majority
Close meeting	I move to adjourn.	No	Yes	No	No	Majority